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ENVIRONMENTAL PROTECTION AGENCY

40 CFR PARTS 153 and 159

[OPP-60010C; FRL-4984-2]

Reporting Requirements For Risk/Benefit Information

AGENCY: Environmental Protection Agency (EPA).

ACTION: Draft final rule.

SUMMARY: This final rule codifies EPA's interpretation and enforcement policy regarding section 6(a)(2) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), which requires pesticide registrants to report information concerning unreasonable adverse effects of their products to EPA. The purpose of the rule is to clarify what failures to report information, or delays in reporting, will be regarded by EPA as violations of FIFRA section 6(a)(2), actionable under FIFRA sections 12(a)(2)(B)(ii) and 12(a)(2)(N). In comparison to previous EPA policy statements, some reporting requirements are expanded, and others have increased flexibility or exemptions for reporting specific types of information. When effective, this rule will supersede all previous policy statements pertaining to section 6(a)(2).

EFFECTIVE DATE: This rule will become effective [insert date 270 days after date of publication in the FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: By mail:

James V. Roelofs,
Office of Pesticide Programs (7501C),
U.S. Environmental Protection Agency,
401 M St., SW.,
Washington, DC 20460.
Office location, telephone number, and e-mail address:
Crystal Mall II, Rm. 1113,
1921 Jefferson Davis Highway,
Arlington, VA, (703) 308-2964,
e-mail: roelofs.jim@epamail.epa.gov

SUPPLEMENTARY INFORMATION:

This Federal Register document discusses the background of this final rule concerning the reporting of adverse effects information by pesticide registrants; addresses in general terms the main public comments on the provisions of the proposed rule published in the Federal Register of September 24, 1992(57 FR 44290); provides EPA’s final determination with respect to the provisions of the final rule; and provides information on the applicable statutory and regulatory review requirements. A more detailed section-by-section discussion of the public comments on the proposed rule and the Agency’s response thereto can be found in "Agency Response to Public Comments" in the public docket.

This document is organized into 3 units. Unit I provides background on the relevant statutory provisions and the regulatory history of adverse effects reporting. Unit II contains a discussion of the final rule and EPA's response to the major comments submitted on the proposed rule. Unit III discusses compliance with the rulemaking requirements contained in FIFRA and other statutes and executive orders, followed by the regulatory text.

I. BACKGROUND

A. The Statute

Section 6(a)(2) of FIFRA requires that, "[i]f at any time after the registration of a pesticide the registrant has additional factual information regarding unreasonable adverse effects on the environment of the pesticide, the registrant shall submit such information to the Administrator." Section 6(a)(2) provides an important function by assuring that a previous Agency decision to register a pesticide remains a correct one, and that a registered pesticide can in fact be used without posing unreasonable adverse effects on the environment. Other provisions of FIFRA allow the Agency to require pesticide registrants to develop and submit information the Agency believes it needs in order to evaluate the risks and benefits of pesticide products. Section 6(a)(2), however, provides that registrants must also inform the Agency of certain relevant information relating to their products, even though it was not specifically

requested by EPA. It recognizes that registrants may come into the possession of important information that was not anticipated by the Agency, and that without the submission of such information by registrants, EPA would remain without it. Information reportable under this provision includes not only new information derived from scientific studies, but also reports of incidents of adverse effects resulting from the use of pesticide products. Thus, the section serves to provide an important ongoing check on the correctness of the original decision to register a pesticide.

As a general matter, pesticides may not be sold or distributed in the United States unless they are registered with the EPA (FIFRA section 3(a)). In order to obtain a pesticide registration, an applicant must provide EPA with data (or cite existing data) demonstrating that the proposed registration complies with the requirements for registration (FIFRA section 3(c)(1)(F)). The standard for determining whether an application should be granted is found in FIFRA section 3(c)(5), which provides that in order to grant a registration, EPA must find that a product’s composition warrants the proposed claims for it; that the product’s labeling and other material required to be submitted comply with FIFRA; that the product will perform its intended function without causing unreasonable adverse effects on the environment; and that, when used in accordance with widespread and commonly recognized practice, the product will not

cause unreasonable adverse effects on the environment. FIFRA defines unreasonable adverse effects on the environment as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." Thus, a critical aspect of determining whether or not a pesticide should be granted a registration is an evaluation of whether the benefits associated with the use of a pesticide exceed the risks associated with such use.

The burden of demonstrating that a product meets the standards for registration rests at all times on the registrant or applicant for registration. See, e.g., Industrial Union Dept. v. American Petroleum Institute, 448 U.S. 607, 653 n. 61 (1980); Environmental Defense Fund v. EPA, 510 F.2d 1292, 1297, 1302 (D.C. Cir. 1975). Section 6(a)(2) only imposes a reporting burden on persons who have registered pesticides, and only requires reporting of information if that information is: (1) additional; (2) factual; and (3) regards unreasonable adverse effects on the environment of the pesticide. These three factors were much discussed in the comments submitted on the proposed rule.

B. Previous Regulatory Interpretations of Section 6(a)(2)

1. 1978 Interpretive Statement. On August 23, 1978, EPA published in the Federal Register (43 FR 37611) its

interpretation of the requirements imposed by section 6(a)(2). In that Interpretive Statement, EPA focused on the meaning of two of the three factors pertaining to whether information is reportable: what information is "regarding" unreasonable adverse effects on the environment, and what information can be said to be "factual." EPA went on to make clear that it believed information must be submitted under section 6(a)(2) if a registrant possesses the information, the information pertains to a pesticide for which the registrant holds a registration, and "the information, if true, would be relevant to an Agency decision regarding the risks and benefits of the pesticide, i.e., an Agency decision regarding the registrability of the pesticide or regarding the proper terms and conditions of the registration of the pesticide." The Statement went on to say that reportable information need only "pertain or relate to unreasonable adverse effects on the environment; it does not have to indicate, establish, or prove the existence of such effects." EPA made clear in the Statement that a registrant need not determine that the information would result in a change in the terms and conditions of registration in order for information to be reportable, because the ultimate determination on such registration issues rests with EPA. If the information would be relevant to the Agency’s decision-making on whether a pesticide should remain registered and, if so, under what terms and conditions, the information "regarded" unreasonable adverse effects on the environment.

In terms of the definition of "factual", the Agency explained that there was no clear demonstration of congressional intent concerning the scope of the information, and that the Agency would therefore interpret the term based upon the function of section 6(a)(2) in the context of FIFRA's regulatory scheme. Since EPA routinely relies on expert opinion in order to make regulatory decisions, and since "Congress recognized that protection of the health of the public and the environment cannot wait until evidence of unreasonable adverse effects becomes conclusive or universally accepted", EPA determined that "factual" information should be interpreted broadly to include opinions if the opinions were not "the unsolicited opinions of persons who are not employed or retained by the registrant to express the opinion and whose opinions would not be admissible under the Federal Rules of Evidence as 'expert' opinion" (Id. at 37613).

2. 1979 Policy Statement. On July 12, 1979, EPA published in the Federal Register (44 FR 40716) a Statement of Enforcement Policy regarding registrants' obligations under section 6(a)(2). That Statement did not curb the scope of section 6(a)(2) as enunciated in the 1978 Interpretive Statement, but instead indicated that certain information arguably pertinent to the evaluation of the risks and benefits of a pesticide "are not currently needed by EPA in order to properly discharge its statutory responsibilities under FIFRA and thus need not be

submitted by registrants." The Policy Statement notified registrants of the types of information for which a registrant's failure to report might precipitate enforcement action by EPA. In other words, the Policy Statement announced as a matter of enforcement discretion that certain types of information need not be submitted by registrants notwithstanding the fact that the information fell within the scope of section 6(a)(2). EPA indicated that it would honor the exemptions from reporting contained in the Policy Statement until at least 30 days after a modification or revocation of the Policy Statement was published in the Federal Register. The Final Rule published today constitutes a revocation of that Policy Statement; the 1979 Policy Statement will cease to be Agency policy on **[insert date 270 days after date of publication in the Federal Register].**

3. 1985 Interpretive Rule. On September 20, 1985, EPA published in the Federal Register (50 FR 38115) a Final Interpretive Rule and Statement of Policy concerning reporting obligations under section 6(a)(2). The rule identified those types of information covered by section 6(a)(2) for which enforcement action would be brought if material were not submitted to the Agency, and exempted the reporting of other information covered by the statutory provision. It is not clear whether the Interpretive Rule ever became effective. The Federal Register Notice provided that EPA would publish in the Federal Register a notice announcing the effective date of the rule, but

no subsequent notice was ever published. In light of the issuance of this new Final Rule, the issue of whether the 1985 Rule ever became effective need not be resolved.

4. The 1992 Proposed Rule. On September 24, 1992, the Agency published in the Federal Register (57 FR 44290) a Proposed Rule relating to the submission of information pursuant to section 6(a)(2). The preamble to that rule discussed in detail the Agency's interpretation of section 6(a)(2) and the rationale for the provisions of the Proposed Rule. Many of those provisions have not changed significantly in the Final Rule being published today. The Agency continues to endorse the substance of the preamble to the Proposed Rule. EPA has not always repeated in this preamble material addressed in the Proposed Rule; the discussion in that preamble is incorporated into this preamble by reference, and should be consulted by anyone seeking additional background on the decisions reflected in this Final Rule.

C. Current Interpretation of Section 6(a)(2)

In assessing the proper scope of section 6(a)(2), it is necessary to focus on the potential regulatory actions that the Agency can take under FIFRA in its continuing evaluation of whether a pesticide poses unreasonable adverse effects on the environment. The potential cancellation or suspension of a

registration pursuant to section 6 is the most restrictive action EPA can take against a pesticide registration, and these were the regulatory activities most discussed by commenters on the proposed rule. While reportable information under section 6(a)(2) could conceivably result in cancellation or suspension action, this information could also be used by the Agency in other ways. The information could suggest the need for modifications to the terms and conditions of registration which could be necessitated by the balancing of the risks and benefits associated with a particular pesticide. It could also identify information gaps that could result in the request for additional information from registrants pursuant to section 3(c)(2)(B). Finally, it could identify to the Agency pesticides and issues that require closer examination by the Agency.

The Agency thus takes a very broad view of the statutory scope of section 6(a)(2). Although EPA interprets the section as requiring the submission of potentially large amounts of information, the Agency is also sensitive to the burden this could put on both registrants and Agency reviewers. Accordingly, this Final Rule identifies the material that the Agency considers relevant to determining whether a registered pesticide continues to meet the standards of registration and wants to be submitted under section 6(a)(2), and essentially exempts from the reporting requirements information not covered by the Rule.

This Final Rule establishes requirements on what information must be reported, when and how the information must be submitted to the Agency, and who has reporting obligations. The nature of the information that must be reported was the principal focus of most of the comments and takes up the bulk of the final rule. Most of this portion of the rule is considered by the Agency to be interpretive in nature and similar to the policy statements issued on section 6(a)(2) in the past. The primary sources of information covered by the rule are scientific studies, reports of incidents involving pesticides, and certain opinions, but other information could also be included if relevant to the risk/benefit balancing involved in the determination of whether a pesticide causes unreasonable adverse effects on the environment.

A number of general comments argued the need for registrants to investigate and verify the validity of information before reporting. The Agency manifestly did not design this Final Rule to cover only information certified to be valid. Especially in the area of incident reporting, the Agency recognizes and accepts that many reports may prove not to be valid. Registrants are not obligated to investigate, analyze, or verify incidents before reporting to the Agency, and EPA accepts that a reporting registrant may well disagree with either the significance or validity of incident reports. Registrants are free to submit information challenging the validity of 6(a)(2) information

either at the time of, or after submission of the information to the Agency. In order to comply with the Final Rule, however, registrants must submit the required information promptly. Failure to submit information because of the incompleteness of ongoing investigations will be considered a violation of both this Final Rule and of FIFRA.

Finally, EPA wants to serve notice that failure to comply with the requirements of section 6(a)(2), as reflected in this Final Rule, will be considered a violation of FIFRA sections 12(a)(2)(B)(ii) and 12(a)(2)(N), and could result in actions for civil and/or criminal penalties under FIFRA section 14. Failure to comply with these requirements may also constitute grounds for cancellation under FIFRA section 6 of some or all of a registrant’s pesticide registrations, both because such failure means that "material required to be submitted does not comply with the provisions of [FIFRA]" and because the Agency may conclude that the registrant has failed to carry its burden of demonstrating that the use of its pesticides do not pose unreasonable adverse effects on the environment. EPA does not intend to pursue cancellation every time section 6(a)(2) may have been violated, but egregious or repeated violations may warrant cancellation rather than, or in addition to, monetary fines.

II. Section-By-Section Discussion

Comments were received on virtually every provision of the 1992 Proposed Rule. As noted earlier, the Agency's detailed response to the comments is contained in a document entitled "Agency Response to Public Comments" which is available in the public docket for this rule. The discussion in this unit is limited to pointing out significant changes to the provisions of the proposed rule, or to responding to comments that are, in the Agency's judgment, particularly important to clarify.

A. Section 159.153 - Definitions

This section provides a number of definitions applicable to the Final Rule. Three definitions in particular were subject to a number of comments. Each is addressed in turn.

"Pesticide" - The definition of pesticide in the Proposed Rule included "each active ingredient, inert ingredient, impurity, metabolite, or degradate contained in, or derived from, a pesticide product which is or was registered." A number of commenters argued that this definition is excessively broad, impractical, and in violation of FIFRA (which defines the term pesticide more narrowly). The Agency has considered the comments, and determined to retain the definition of "pesticide" contained in the Proposed Rule. A slight change was made to include the word "contaminant" in the definition as well.

The focus of the statutory definition of "pesticide" is to define what products must be registered. The definition is one of intent -- essentially a product must be registered if it claims to control pests. This is distinctly different from the question of what information about those products has to be submitted to EPA in order to make the risk and benefit determinations required to establish or maintain registrations. So long as the use of the pesticide results in an adverse effect, it is irrelevant for purposes of whether the information must be submitted whether the effect is actually caused by an active ingredient, an inert ingredient, or a metabolite, degradate, impurity, or contaminant. In fact, some pesticide risk assessments have been based in whole or in part on the risks posed by contaminants, such as dioxins in certain herbicides, or metabolites such as ethylene thiourea (ETU) in the EBDC fungicides.

In short, the Agency does not believe it can be seriously argued that adverse information about the inert ingredients, metabolites or contaminants in a pesticide product is outside the statutory scope of what must be reported under section 6(a)(2), or that it is inconsistent in any way with the statutory definition of a pesticide. Moreover, this interpretation is consistent with section 10(d) of FIFRA, which clearly contemplates that the Agency may require registrants to submit for the purpose of registering pesticide products information on

a product's "separate ingredients, impurities, or degradation products" as well as information on the product itself.

EPA recognizes that this definition of pesticide may pose a problem for registrants who do not know the identity of inert ingredients in their products, or for large organizations where the applicability of inert ingredients, metabolites, or degradates to particular pesticide products may not be appreciated by those individuals who obtain adverse information concerning an inert, metabolite, or degradate. In any particular enforcement action that might arise under section 6(a)(2), EPA will consider these factors, as well as the steps a registrant has taken to assure that adverse effects information on both pesticide products and particular chemicals or metabolites is referred to the appropriate personnel in the company.

"Registrant" - The definition of "registrant" in the Proposed Rule included any person who "holds or ever held" a pesticide registration. A number of commenters have challenged the authority of the Agency to apply the requirements of section 6(a)(2) to persons that held, but no longer hold, pesticide registrations. Some commenters argued that former registrants should be excused from reporting obligations after a set period of time (e.g., 3 or 5 years). Other commenters suggested that EPA extend the definition to include persons given emergency exemptions pursuant to section 18 of FIFRA.

EPA has changed the definition of "registrant" to clarify that the definition includes agents acting for a registrant. The Agency did not change the definition insofar as it applies to former registrants, although certain exemptions have now been established to limit the requirements on former registrants (see below). EPA explained in the preamble to the Proposed Rule its belief that section 6(a)(2) could be interpreted to put a continuing burden on registrants after a product registration is canceled or transferred. In the case of a transferred registration, for example, the pesticide product may continue to be widely used. Even in the case of canceled products, existing stocks may continue to be sold or used for a long period of time. Thus, the Agency's responsibilities with respect to whether sale or use of a pesticide should be permitted and, if so, under what conditions, do not necessarily end when a registration is sold or canceled. A former registrant may continue to receive information about its former products from consumer complaints or information about accidents well after a product is canceled or transferred. So long as this information can affect continued Agency decision-making with respect to the once-registered product, EPA believes relevant information in the hands of former registrants must be provided to the Agency.

EPA has decided not to impose a general cutoff for reporting by former registrants for two reasons. First, EPA lacks sufficient information to be able to identify an appropriate

cutoff point. Second, EPA believes that the burden on former registrants will generally diminish significantly over time, as the time from cancellation or transfer increases.

In order to minimize the burden on former registrants somewhat, the Agency has added a new section (§ 159.160) that provides that for former registrants who have entirely left the pesticide business, i.e., hold no active pesticide product registrations, adverse information associated with their formerly held registrations need only be reported for one year after they cease to hold any active registration. For a person who continues to hold active pesticide registrations, and may therefore be likely to continue to receive adverse information even about formerly registered products, this rule provides that information need not be reported if it is associated only with inert ingredients, contaminants, impurities, metabolites, or degradates contained in formerly registered products and is obtained more than 3 years after the registrant first ceases to hold the registration. Former registrants will still be required to report adverse information involving the formerly-registered pesticide product itself, as well as information involving any of the active ingredients contained in the formerly-registered product. If a registrant finds that the requirement to submit information on formerly-registered pesticides is imposing a substantial burden, the registrant may request relief from the Agency pursuant to § 159.155 of the regulatory text.

As to expanding the scope of coverage to holders of exemptions issued pursuant to section 18, the Agency does not believe that such holders are "registrants" within the meaning of FIFRA, and they are thus outside the statutory scope of section 6(a)(2). The Agency does have the authority to include adverse information reporting requirements as part of a section 18 exemption, and the Agency already considers this issue as part of its review of requests for such exemptions.

The Agency believes that supplemental distributors operating pursuant to 40 CFR 152.132 are agents acting for a registrant, and are already covered by section 6(a)(2). Failure of a supplemental distributor to report adverse effects information otherwise covered by this Final Rule can result in enforcement action against both the supplemental distributor and the parent registrant. Regarding agents, the Agency has always considered registrants responsible for the actions of their agents. Clarifying language has been added to the regulatory text to emphasize that registrants will be held liable for the actions of their agents. The new language also makes it clear that for the purposes of reporting under this rule, the Agency considers an agent of the registrant to be a person who is likely to receive information about the effects of pesticides, and who is acting for the registrant at the time the information is received. Such agents could include consultants, contract laboratory researchers, attorneys, investigators, and others. However, the

Agency does not consider every direct or indirect employee of a registrant as likely to receive such information. Financial and personnel workers, or even workers in a pesticide manufacturing plant, for example, would not be dealing with pesticide effects information nor would they normally be in contact with product users or other persons who are likely to report pesticide effects information.

"Water Reference Level" - The water reference level is the level at or above which the Agency wants to be informed of a pesticide's presence in surface water or groundwater. The Proposed Rule defined water reference level as the limit of detection of a pesticide in water; or alternatively, 10 percent of the Maximum Contaminant Level (MCL) if one has been established by EPA, 10 percent of the most recent draft or final long-term Health Advisory Level (HAL) if there is no MCL, or the lowest detectable amount if there is neither an MCL nor an HAL. Commenters that raised objections to the water reference level argued that the level would result in excessive reporting to the Agency. Commenters suggested that the reference level be set at the MCL or HAL itself rather than at a fraction of the level; the same commenters generally observed that since pesticides for which there is neither an MCL nor an HAL pose less of a concern, the reference level for those should not be set at so low a level as the level of detection.

The terms of this Final Rule are substantially similar to those of the Proposed Rule. Given the persistence of some pesticides and the sketchy nature of the monitoring of pesticides in surface water and groundwater, the Agency does not believe it appropriate to set the reference level at the MCL or HAL. EPA believes an earlier warning of potential problems with pesticides in water is appropriate and has therefore determined to retain the reference level at 10 percent of the HAL or MCL. The Agency has also decided to retain the level of detection as the reference level for pesticides that have not been assigned an MCL or HAL. EPA believes that, until it has sufficient information about the likelihood of a pesticide making its way into water, it should receive information about detections in water at the earliest possible stage. However, the Agency did modify this provision so that the default requirement to report “the lowest detectable amount” when there is no MCL or HAL for a compound does not apply to metabolites, degradates, contaminants or impurities. Detections in water of these components of a pesticide need only be reported when the Agency has identified a specific level of concern in water.

EPA did make one other significant change in the Final Rule’s definition of water reference level. The MCL and HAL levels are based on human toxicity triggers; neither level takes into account the toxicity of pesticides to other life forms. In order to be consistent with other Agency policies related to the

protection of water quality, the Agency added to the definition of "water reference level" the Ambient Water Quality Criteria for the Protection of Aquatic Life, established under the authority of section 304(a) of the Clean Water Act. If EPA has established such criteria for a specific pesticide, and that level is lower than 10 percent of the MCL or HAL, then the water quality criterion is the reportable reference level. For a compound which is detected in water, the Agency believes the reporting level should be whichever threshold is the most protective of the environment, whether that is the MCL-based trigger derived from estimated toxicity to humans, or water quality criteria derived from estimated risk to aquatic life. Water Quality Criteria documents for over one hundred individual compounds, including some pesticides, are published by the Agency and are available from the National Technical Information Service (NTIS) in Springfield, Virginia (telephone 703-487-4650).

B. Section 159.155 - When Information Must Be Submitted

The Proposed Rule required that reportable information be submitted to the Agency within 30 calendar days of the registrant’s first becoming aware of the information. A registrant would be considered aware of information when any officer, employee, agent, or other person acting for or employed by the registrant first comes into possession of, or knows of,

such information. These provisions are unchanged in the Final Rule.

A number of commenters objected to the provision that a registrant would be deemed to possess information if any person acting for or employed by the registrant possesses or knows of the information. Instead, these commenters suggested that it would be more appropriate for the Agency to retain the standard contained in the 1985 Interpretive Rule, which provided that a registrant possesses or knows of information only when the information is possessed or known of by a person acting for or employed by the registrant who is "capable of appreciating the significance of such information."

The Agency does not agree with these comments and has retained the requirement as proposed. The Agency is concerned that the "capable of appreciating" standard would lead to disputes over whether a particular individual is or is not capable of appreciating the significance of information in any particular instance. A registrant should take steps to assure that the results of studies performed by the registrant or at the registrant’s request are reported promptly to someone responsible for assuring compliance with section 6(a)(2). Similarly, EPA believes that most registrants probably already have particular individuals designated to receive and/or respond to consumer complaints. The Agency does not believe it is unfair to place

upon registrants the burden of assuring that such complaints are routed to people who understand the reporting requirements of section 6(a)(2).

The Agency recognizes that even when a registrant has established a reasonable system for tracking reportable information, information may nonetheless be received by individuals working for that registrant who neither appreciate its significance nor pass it on to personnel who would. The Agency anticipates that its enforcement response to such situations will likely depend upon the identity of the person receiving the information and the steps taken to assure compliance with section 6(a)(2). For example, if a person submits reportable information to an employee of a pesticide registrant that could reasonably be expected to receive the information, such as a sales representative or a person who takes phone calls from the public, the Agency believes that such an employee should be expected to transmit the information to the appropriate personnel working for the registrant, and the Agency would likely take enforcement action for failure to report such information within the 30-day period.

C. Section 159.156 - How Information Must Be Reported

This section establishes guidelines for how reportable information must be submitted to the Agency. A number of minor

modifications were made in order to clarify the procedures for identifying and submitting information pursuant to section 6(a)(2). The most significant comments on this section concern summaries and issues involving confidentiality of information.

Section 159.156(f) - The requirement to summarize information concerning a study or incident is one that received a great deal of comment, and one that the Agency has modified from the Proposed Rule. Commenters raised a number of objections to the proposed requirement that registrants summarize "all known information" concerning a study or incident on numerous grounds, including that the requirement exceeded the Agency’s statutory authority, that it would be unreasonably burdensome, that it would result in the submission of excessive, extraneous, and unreliable information (especially with regard to incidents), that it could be construed as an admission by a registrant that the information contained in a report (particularly an incident report) is correct, and that it could adversely affect the ability of a registrant to obtain information that might be considered proprietary, privileged, or confidential by someone because such information would have to be turned over to EPA.

The Agency has retained a requirement to summarize information, but in the Final Rule is providing significant additional guidance on what information needs to be included, and what does not need to be included, in such summaries. It will

enable the Agency to quickly ascertain the nature of the information being reported and therefore more quickly and responsibly fulfill its responsibilities under FIFRA.

The Agency does not believe that a summary ought to be construed as an admission by a registrant that the information reported to a registrant and contained in the summary is true and correct. The standard for reportability is not whether the registrant believes a report submitted to it is factual and accurate. The report itself will not automatically be taken by the Agency as an admission by a registrant that it concedes the correctness of information contained in an allegation. Registrants are free to provide with their submissions any information they deem appropriate which may qualify or contest a reported allegation of adverse effects.

As to the suggestion that the Proposed Rule might hamper registrants' ability to obtain information from individuals, the Agency has little way of knowing whether individuals might not cooperate with registrants or provide them with much information they currently provide if those individuals know that the information might be passed on to EPA. EPA's treatment of any information would be governed by FIFRA section 10 (which involves treatment of Confidential Business Information (CBI) under FIFRA) and by the Freedom of Information Act (FOIA). If the information is not protected under section 10, and if it is not withholdable

under FOIA, EPA would be obligated to make it available to members of the public upon request. On the other hand, FOIA does allow agencies to withhold from release medical files and similar material the disclosure of which would constitute a clearly unwarranted invasion of personal privacy. Material in a submission which is deemed confidential under FOIA should be segregated from the rest of the submission in the same manner as material deemed CBI under FIFRA section 10. Section 159.156(i) of the regulatory text refers submitters to the already existing procedures for segregating material deemed confidential.

The Agency does not believe it would be appropriate, as some commenters suggested, to delegate to registrants the determination of whether the information in any particular case is so significant that it should be provided to the Agency. As the United States District Court for the District of Columbia found in the case of CSMA v. EPA, 484 F.Supp. 513 (1980), this determination belongs to EPA rather than to the regulated community. Under the circumstances, EPA cannot allow registrants to withhold otherwise reportable information on the grounds that persons who submitted it to the registrant might prefer that it not be transmitted to EPA.

In regard to summaries themselves, EPA agrees that the proposed rule was too vague and could have lead to reporting of excessive or extraneous information. The Agency also is

sensitive to the need to provide registrants with more guidance on what and how to summarize.

The new paragraph (f) makes the following changes. First, it refers only to incident reporting, and not laboratory studies. Studies are already subject to requirements that they be identified as 6(a)(2) information, both by the terms of this rule at § 159.156, and by the existing "flagging" criteria for certain toxicity studies at 40 CFR 158.34. This will generally be sufficient for an initial determination of whether the study warrants an expedited scientific review. Thus, a further requirement for summarization is unnecessary. This is clearly not the case for incident information.

Incident information may come to a registrant in many different forms, ranging from consumer complaints by telephone, to detailed investigative reports developed in connection with a lawsuit. After considering all comments on this issue, the Agency has decided to identify the specific items of factual information that would best enable EPA to evaluate quickly and accurately the nature and seriousness of the incident being reported. These data elements vary by type of incident, and are listed in the revised §159.184, which deals with incident reporting. The revised §159.156(f) simply refers the registrant to §159.184.

It must be stressed that the information identified in §159.184 constitutes the optimal set of information the Agency would like to have regarding different types of incidents. If a registrant does not possess certain information, it is under no obligation to commence an investigation or to otherwise generate or obtain the information. Registrants need only include in summaries those pieces of information which are both requested in this Final Rule and which they possess. If a registrant comes into possession of an additional piece of information that would have been included in the original summary, the registrant must submit the additional information in a second summary within 30 days of receipt, and reference the earlier submission.

Paragraph (i) -- In the Proposed Rule, confidentiality was dealt with in paragraph (g). As a general matter, the confidentiality of information submitted pursuant to the Final Rule is governed by section 10 of FIFRA and by the Freedom of Information Act. Any claim that material submitted pursuant to FIFRA section 6(a)(2) is entitled to confidentiality for reasons related to trade secrets or CBI must be viewed in light of FIFRA section 10. Section 10(d) provides that certain information, including "any information concerning the effects of [a] pesticide on any organism or the behavior of such pesticide in the environment, including but not limited to, data on safety to fish and wildlife, humans and other mammals, plants, animals, and soil" shall be available for disclosure to the public. Section

10 thus makes clear that information concerning the effects of a pesticide on humans or the environment cannot be withheld from the public on grounds of trade secrecy or business confidentiality.

The Agency expects that most material submitted under section 6(a)(2) will continue to be of the type that is not entitled to confidentiality and must be made available to the public pursuant to section 10(d). Accordingly, the Final Rule includes a provision requiring that, if registrants consider any portion of a section 6(a)(2) submittal to be confidential, they specify the portion for which confidentiality is desired; they explain why such portion is entitled to confidentiality under the applicable provisions of FIFRA section 10; and they provide a "sanitized" version of the submittal that can be publicly released with the confidential information omitted. The sanitization process is identical to that codified in 40 CFR 158.33, and which has applied for years to data submitted to the Agency by pesticide registrants. The new paragraph (i) refers registrants to §158.33 for the appropriate procedures to handle confidentiality claims.

The Agency is preparing a notice in the form of a class determination to registrants which will inform them that the Agency will not honor routine business confidentiality claims for

material submitted pursuant to section 6(a)(2) and covered by the disclosure provision of section 10(d).

Some commenters suggested that the Agency exempt from the reporting requirements of section 6(a)(2) material covered by the attorney-client or attorney work-product privileges. The Agency is extremely concerned with the implications of broadly exempting information covered by the attorney work-product doctrine. Exempting attorney work-product from section 6(a)(2) reporting would make the reportability of investigative work hinge on whether the work was generated at the suggestion of an attorney or of a non-attorney associated with a registrant. The Agency does not believe there is any valid policy reason to exempt from section 6(a)(2) reporting valuable information merely because it was developed at the suggestion of an attorney.

Although the Agency does not know what useful information, if any, might be covered by the attorney-client privilege, the same logic applies as to the work-product doctrine. EPA does not believe it should make registration decisions based upon incomplete information in order to avoid the possibility of affecting registrants' positions in litigation.

The commenters raising this issue did not argue that information covered by the attorney work-product doctrine or the attorney-client privilege is outside the statutory scope of

section 6(a)(2). Instead, these commenters suggested that the Agency as a matter of policy craft an exemption for such material from the statutory reporting requirements. This the Agency declines to do. However, a registrant is always free to notify the Agency of its possession of potentially privileged information which falls under the scope of section 6(a)(2) and request that the Agency not require the submission of certain specified information in a particular case. EPA is not committing to grant such requests, but neither does it rule out the possibility of exempting otherwise submittable information in particular circumstances where it can be shown that the information is entitled to some privilege, that providing it to the Agency would substantially prejudice a registrant, and that the information would not be helpful to an analysis of a product's registration status. No such request will be honored unless it is made in writing and sent or delivered to one of the addresses listed in § 159.156 of this Part, and been granted in writing by a responsible Agency official.

D. Section 159.157 - Recordkeeping Requirements

The Proposed Rule provided for 5 years of record retention for most types of information submitted to comply with the rule, but 10 years retention for certain information, such as information alleging adverse effects to one or two human beings. These retention periods were intended, in part, to enable

registrants to determine whether information on certain incidents, which would not have been reportable by itself, would turn out in time to be part of a series of three similar incidents, and would thus have become reportable under the provisions of the Proposed Rule. Since the “series of three” concept has been dropped from this rule, the different record keeping requirements no longer have any purpose, and are deleted from all sections of this rule where they were previously mentioned. The question remains whether any record keeping should be required. The Proposed Rule provided that a copy of any submission to the Agency, and proof of delivery to the Agency, be retained for 5 years. The Agency considers all information derived from a reportable incident to fall within the scope of section 6(a)(2), but believes that if summaries are provided, additional information will rarely be needed. The Agency also believes that most registrants will retain records of adverse information reported to them for their own needs, and the Agency recommends that they do so. The Agency has concluded, however, that there is little value to EPA in having registrants retain copies of their submissions, and therefore has eliminated this requirement entirely.

E. Section 159.158 - What Information Must be Submitted

This section provides guidance on what particular types of information must be submitted. The Proposed Rule contained four

paragraphs. For clarity, the Agency has restructured § 159.158 into only two paragraphs; paragraph (a) identifies the general requirements formerly contained in (a) and (b) of the proposed rule, and the new paragraph (b) describes the exceptions to reporting requirements formerly contained in paragraphs (c) and (d). The most significant issue for this section concerns opinion information.

A number of commenters objected to proposed §159.158(b), arguing that opinion information is not factual information, and thus is not subject to the reporting requirements of section 6(a)(2). As support for this objection, they cite the case of CSMA v. EPA, supra, in which the court opined that opinion information was not subject to reporting under section 6(a)(2).

EPA has determined to retain the proposed provision without change in the Final Rule. As stated in the preamble to the Proposed Rule, the Agency does not believe that the issue of opinion information was properly before the District Court in the CSMA case or was any part of the holding or basis for the decision in the case. The Agency also believes that, if the issue were presented to a court today, certain types of opinion information would be found within the scope of section 6(a)(2).

As noted in the preamble to the Proposed Rule, the Agency is frequently obliged to make decisions in at least partial reliance

on expert opinion. Indeed, often the Agency must resolve scientific issues under a "weight of evidence" approach, because the state of science makes a more definitive resolution impossible. For example, a conclusion as to whether a particular growth seen in a sacrificed test animal is a benign or malignant growth is not a matter of uncontestable fact, but rather, is the expression of an informed judgment by a trained professional (i.e., an expert opinion). Such expert opinions often serve as the basis for subsequent decisions about whether a chemical might pose a cancer risk to humans. These conclusions are based on a combination of observations and expert opinions; experts can and do disagree, and no conclusion can be considered indisputable fact. Yet such opinions play an important role in whether a pesticide should be registered and under what conditions. Indeed, studies submitted by registrants or applicants for registration frequently contain the conclusions and opinions of experts concerning the results and import of those studies. Where those conclusions and opinions suggest that a pesticide may pose a significant risk or a risk greater than previously presumed, the Agency believes those conclusions and opinions must be reported to the Agency pursuant to section 6(a)(2).

In order to be reportable, an opinion must meet two criteria. First, the opinion must relate to information that is relevant to the risk/benefit balance applicable to a particular registered pesticide. Second, the opinion must be from either an

employee or agent of the registrant; a person from whom the registrant requested the opinion; or a person who could be considered an expert with regard to the matter on which the opinion was uttered. The Agency believes opinions from these categories of people are more likely to have credibility and/or warrant further investigation than are opinions from people not falling into these categories.

In terms of whether a conclusion or opinion can be said to have been rendered by an expert, previous publications of the Agency have suggested that registrants should be guided by whether the individual rendering the conclusion or opinion would, by virtue of his or her knowledge, skill, experience, training, or education, be qualified as an expert under Rule 702 of the Federal Rules of Evidence to testify to the opinions or conclusions on the subject at issue.

The Agency considers trained professionals to be experts in their trained field for purposes of section 6(a)(2) reporting. If a medical doctor expresses a conclusion or opinion on a person’s medical condition and the causes of that condition, the conclusion or opinion must be reported, regardless of whether the registrant believes the information to be valid or correct, or whether the registrant believes the expert performed an appropriate investigation upon which to base the conclusion or opinion. It must be left to the Agency to evaluate the validity

of the conclusion or opinion and determine the appropriate response to the information.

Finally, this discussion of expert opinion does not mean that the Agency intends to exclude reports of adverse effects in cases where an average person would reasonably suspect that pesticide exposure was a likely cause. For example, where someone develops tremors shortly after using a pesticide, common sense would suggest a link between pesticide exposure and the effect. Such an event would be reportable, even if it were not brought to the attention of a trained professional.

Many commenters noted that the Proposed rule would have required the submission of published information, while the 1985 Interpretive Rule exempted from the reporting requirements any information contained completely in "any scientific article or publication which has been abstracted in Biological Abstracts, Chemical Abstracts, Index Medicus, or Pesticides Abstracts" if the abstract clearly identified the active ingredient or registered pesticide to which the information pertains.

In response to comments, the Agency has decided to exempt from reporting requirements articles and publications which are abstracted in the identified abstracts, except that information in any scientific articles or published literature (including those abstracted in the identified abstracts) must be reported if

that information pertains to epidemiological studies and incident reports. EPA is singling out these types of information for reporting because they are of particular value to the Agency in assessing the risks associated with use of a pesticide and because these types of information are often not readily available to the Agency.

F. Section 159.159 - Information Obtained before Promulgation of the Rule

The Agency added this new section in order to address the issue of reporting previously-obtained information raised by a number of commenters. The proposed rule did not address this issue. If the final rule were silent on the issue, then under the terms of the rule as originally proposed, any previously unsubmitted information which became reportable under the final rule would have to be submitted within 30 days. Such a requirement would probably not be feasible for registrants or EPA. The Agency has decided to limit the scope of reporting previously-obtained information in a number of ways.

For studies reportable under §§ 159.165, 159.170, 159.179, or 159.188, the rule limits reporting to studies completed within 5 years of the effective date of this rule. It should be understood that registrants are already required to comply with the obligation to report toxicology studies, failure of

performance for health-related products, and other information required by previous Agency policy statements and guidance concerning 6(a)(2) information. The 5 year limitation established in this paragraph does not relieve any registrant of liability for failure to report information that should have been submitted under previous statements of 6(a)(2) policy.

The 5 year limitation is based on the pragmatic considerations that: (1) older information is, in some cases, relatively less valuable for making risk/benefit determinations than recent information; and (2) the Agency needs to establish some practical limit on the potential demands that additional submissions may make on its resources for reviewing 6(a)(2) submissions. Particularly in the case of incident information, older reports are more difficult to verify, and may also be associated with uses or products that have subsequently changed or have been discontinued.

To further limit the burden of reporting previously obtained information, the new §159.159(a)(2) provides that incident reporting be limited to human hospitalizations or fatalities, and domestic animal or non-target wildlife fatalities only, since these categories of incident information are particularly likely to be of regulatory significance to the Agency.

Section 159.159 further eases the burden of reporting previously held information by providing 1 year for registrants to respond, and also providing that registrants may first submit an inventory of reportable material, rather than submitting actual studies or individual incident reports. This will enable the Agency selectively to decide when to ask for more detailed submissions if it seems likely that information valuable for regulatory decision-making can be retrieved. As described in §159.159(b)(2), an inventory is a simple listing of the kind of individual studies available, or the gross number and kind of incidents associated with a particular ingredient or product.

G. Section 159.160 - Exception Relating to Former Registrants

This new section was added to clarify that former registrants are not obligated to report adverse information on their formerly-registered products more than 1 year after they cease to hold the registration, provided that they hold no active pesticide registrations. A former registrant who has entirely left the pesticide business is considered unlikely to receive reportable information. For a person who continues to hold one or more active pesticide registrations, information need not be reported if it is associated with inert ingredients, contaminants, impurities, metabolites, or degradates contained in formerly-registered products more than three years after the registrant first ceases to hold the registration. Former

registrants who still hold one or more active registrations will still be required to report adverse information involving the formerly-registered pesticide product itself, as well as information involving any of the active ingredients contained in the formerly-registered product.

H. Section 159.165 - Toxicological and Ecological Studies

This section identifies the parameters for reporting information from toxicological and ecological studies. The Proposed Rule dealt with toxicological and ecological studies together, and provided that the results of an incomplete or complete study of the toxicity of a pesticide to any human or non-target organism be reported if it showed a toxic effect, when compared to a previously submitted, valid study: (1) in a different organ or tissue of the test organism; (2) at a lower dosage, or after a shorter exposure period, or after a shorter latency period; (3) at a higher incidence or frequency; (4) in a different species, strain, sex, or generation of test organism; (5) by a different route or medium of exposure; or, (6) through a different pharmacokinetic, metabolic, or biological mechanism.

Many commenters argued that EPA should only require the submission of studies that show significantly greater or different toxic effects than previously submitted studies. In particular, they suggested that the Agency not require studies

showing a similar toxic effect in the same species of test organism. Commenters also suggested that the Agency not require the submission of acute toxicity studies unless the information would result in a change in toxicity category of the chemical.

In response to some of these comments, the Agency has made a number of changes in the Final Rule. The most significant revision is that EPA has established separate standards for studies designed to determine the toxicity of pesticides to humans (revised paragraph (a)), and for studies designed to determine the toxicity of pesticides to non-target plants and wildlife (new paragraph (b)). The requirements for submission of toxicological studies are not substantially changed. However, this Final Rule exempts reporting of acute toxicity studies if the results would not lead to a more restrictive toxicity category for labeling as provided in 40 CFR 156.10(h).

The Agency has made greater changes in the requirements for submission of ecological studies. The proposed rule simply referred to "non-target organisms" and applied the same standards as for studies relating to potential human toxicity. The new paragraph (b) specifies what the Agency wants in the areas of acute toxicity, chronic toxicity, and phytotoxicity. The Agency believes these revisions will give much clearer guidance to registrants, and result in submissions most likely to be of value to Agency decision-making. The Agency has also provided some

flexibility in relation to acute toxicity studies using the same or similar species, and in relation to submitting certain incomplete studies.

I. Section 159.170 - Human Epidemiological and Exposure Studies

The Proposed Rule required that registrants submit any information concerning any study upon which a person described in §159.158(b) has concluded, or an expert would conclude, that a positive correlation or association may exist between exposure to a pesticide and either a toxic effect in humans or residues of the pesticide in human tissue or body fluid, whether or not the registrant considers any observed correlation to be significant. This provision is largely unchanged. The Final Rule slightly modifies the description of exposure monitoring studies; such studies are reportable if they indicate exposure which is higher than indicated by previously available reports, data, or exposure estimates.

J. Section 159.178 - Information about Pesticides on Food or Feed, or in Water

The Proposed Rule would have required the reporting of information by registrants relating to the presence of pesticides in food or feed if the level of pesticide detected in the food or feed was in excess of an established tolerance, food additive

regulation, or action level with the exception of information regarding residues resulting solely from studies conducted under authority of FIFRA section 5 (experimental use permits). Information concerning the presence of pesticides in water would have to have been reported if the presence of the pesticide in most surface waters, groundwater, or drinking water exceeded the water reference level. These provisions are essentially unchanged in the Final Rule. However, this Final Rule has added a provision that residues of metabolites, degradates, contaminants or impurities in water need not be reported unless EPA has identified a specific reference point, such as a draft or final MCL or HAL, or has estimated an HAL based on an established Reference Dose, and notified registrants of that estimated HAL.

A number of commenters thought that the rule as proposed would result in excessive number of reports of questionable value, particularly of detections in water. The Agency recognizes that there may be a large number of detects of pesticides in water, and that the value of each incremental report may be small. The Agency also recognizes that there may be duplicate reports of the same detect submitted by different registrants. The Agency has established water reference levels that are designed to provide EPA with an early warning that a pesticide may be present in water before that presence has reached impermissible levels. In order to assure that the information received is as useful as possible to the Agency, EPA

is requiring summaries of 6(a)(2) reports. The Agency expects that the information called for in the summary of water detects will help guard against double-counting. The Agency also intends to use its authority under §159.155 to require periodic aggregate reporting of detections of pesticides in water if a particular pesticide is the subject of numerous detects.

In response to comments received, the Agency would like to clarify its position on reporting residues of inerts, metabolites, degradates, impurities, or contaminants on food or feed commodities. This issue hinges on whether the presence of the residue on food or in feed would require a tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA). Under the FFDCA, food is considered adulterated if chemical residues are detected on the food unless the chemical residues are covered by a tolerance, or the chemical has been specifically exempted from needing a tolerance, or the chemical is generally considered safe. At 40 FR 180.2, EPA identified a number of chemicals considered "safe" under the meaning of section 408 of the FFDCA, and has also exempted (at 40 CFR 180.1001) a number of substances from the requirements of a tolerance.

K. Section 159.179 - Metabolites, Degradates, Contaminants, and Impurities

The purpose of the section is to ensure that the Agency is informed when registrants learn of toxicologically significant new breakdown products or when they learn of higher levels of contamination than were previously known to be associated with their pesticide products. The provisions of this section are largely unchanged from the proposed rule, with the following exception. In the proposed rule, paragraph (b) limited reporting only to new, previously unreported compounds. As several commenters pointed out, if a previously known contaminant of toxicological concern were discovered at a higher level than previously reported, that would certainly be information relevant to the risks posed by that pesticide. Accordingly, the Agency has corrected this oversight by adding a provision to a new paragraph (c) requiring the reporting of previously known contaminants if they are found at levels higher than previously known to occur. The Agency notes that impurities that occur during manufacture of a pesticide are already subject to certain reporting requirements under the provisions of 40 CFR 158.167 and/or 158.175. For purposes of reporting under the present rule, any detection of a manufacturing impurity at levels greater than the expected level reported to the Agency pursuant to §158.167 or greater than a certified limit established pursuant to §158.175 must be reported as 6(a)(2) information. Both these provisions of part 158 refer only to impurities posing toxicological concerns. In the future the Agency may establish quantified levels of concern for specific classes of

contaminants. In that event, the occurrence of a contaminant covered by such a policy would be reportable if the detected residues were at a level higher than the established level of concern, or if there were information indicating that the contaminant posed significant risks at levels lower than the Agency-established level of concern.

L. Section 159.184 - Toxic or Adverse Effect Incident Reports

One of the most important routes by which adverse effects information can come to the attention of the Agency is through toxic or adverse effect incident reports. Many of the Agency's registration decisions are predictive in nature. In contrast, incident reports can provide the Agency with information depicting the practical impacts of pesticide use, including real-world effects of pesticide use. The Agency considers incident reporting to be a vital component of section 6(a)(2).

The proposed §159.184 imposed different reporting requirements for single incidents as opposed to a series of incidents involving three or more organisms. Incidents involving only one person or nontarget organism were only reportable if the registrant (or other qualified person) had concluded that a causal relationship might exist between exposure to the pesticide and the toxic effect, or if the alleged effect were previously unreported or more severe than previously reported effects. If

the "three or more" trigger was met, an incident or incidents had to be reported without regard to whether the registrant had concluded that a causal relationship existed between exposure and the effect or whether the toxic effect had previously been reported to the Agency.

The proposed §159.184 was the subject of a large number of comments challenging the provision alternatively as too broad as well as too narrow. The Agency reconsidered §159.184 in the light of recent experience, as well as the comments received, and determined that the threshold for reporting incident information needed to be changed and that registrants could benefit from more specific guidance in this preamble.

The provision for reporting incident information in this Final Rule requires the reporting of any single incident involving humans or nontarget organisms if: (1) the registrant has been informed that a person or non-target organism may have been exposed to a pesticide; (2) the registrant has been informed that the person or nontarget organism has suffered or may suffer (or may have suffered) a toxic effect; and (3) the registrant is not aware of facts which establish that the reported exposure did not occur or that the toxic effect did not or will not occur. Individual incidents otherwise meeting this standard need not be reported if: (1) the registrant has been notified by the Agency in writing that aggregate reports may be sent in on a periodic

basis in place of individual reports; (2) the incident involves only non-lethal toxic effects to plants (including nontarget plants and treated crops) which were at the use site at the time the pesticide was applied, if the label provides an adequate notice of such risk; or (3) the incident involves a toxic effect to a pest or pests not specified on the label.

In this Final Rule, the Agency has eliminated the distinction between single incidents and a series of incidents. The Agency also eliminated the requirement, for single incidents, that the registrant or an employee, consultant, or expert, must have determined that the reported effect may have resulted from the reported exposure. These changes were made partly in response to comments received, and partly because the Agency determined that much valuable information was not submitted to the Agency while the higher threshold embodied in previous policies was in effect. Under the Final Rule, incidents must be reported whenever a registrant is informed that a human or other organism has been exposed to a pesticide and the registrant has been informed either that the human or other organism has thereafter suffered an adverse effect or that the exposure that occurred was unexpected and an adverse effect may have occurred thereafter or may occur in the future.

The Agency recognizes that the lower threshold for reporting of incidents contained in this Final Rule might result in the

submission of information which is not sufficiently reliable or detailed to warrant regulatory action. On the other hand, such information might well provide the Agency with advance warning of potential problems and could identify issues that warrant increased review and investigation. The Agency is aware of a number of instances in the past in which information that could well have resulted in regulatory action or investigation was not reported under previous policy determinations on incident reporting under section 6(a)(2). These include instances in which litigation involving allegations of adverse effects caused by pesticide products has not been promptly reported by registrants pursuant to section 6(a)(2).

Registrants should be aware that the Agency considers information related to a lawsuit involving an allegation of adverse effects due to a pesticide to be clearly reportable under the terms of the Final Rule, unless the registrant is aware of facts which establish that the alleged exposure and effect did not or will not occur. The Agency expects to be informed of incident information in a timely manner, regardless of whether the registrant agrees with the substance of the incident report.

In addition to changing the threshold for reporting incident information, the Agency has identified in this section of the Final Rule the information elements that must be included in incident reports if the information is available to the

registrant. For the convenience of both registrants and Agency reviewers, EPA hopes to develop new and more efficient ways to submit this type of information, such as aggregate reporting or direct electronic submission of data. The Agency has elected to delay the effective date of this final rule to nine months after publication primarily in order to work with all interested parties to seek the least burdensome and most efficient ways to implement reporting requirements. Until alternative reporting methods are adopted, the Agency urges registrants to use the simple list format set out in the Final Rule.

As noted earlier, registrants are not obligated to investigate incidents in order to acquire information to satisfy any particular data element; if a registrant lacks information, it does not need to be provided. If, after an initial report is made, a registrant acquires information related to an element previously unreported, or that would significantly modify an element previously reported, the information should be reported and reference the earlier submission.

Unless directed otherwise by the Agency, registrants are not obligated to provide the Agency with any additional information on an incident other than what is summarized in providing the relevant data elements. The Agency may ask for additional information in the registrant’s possession pursuant to §159.195, but in the absence of such a request, providing the information

called for in the data elements is all that a registrant must do in submitting incident information under section 6(a)(2).

Finally, the rule requires the registrant to assign an "adverse effect category label" to each incident. These categories and labels identify the broad nature of the allegation (i.e., the incident involves alleged damage to humans, domestic animals, fish or wildlife, plants, or involves contamination of water), and the severity of the alleged incident. The assignment of a label will not be interpreted by the Agency as agreement by the registrant with the substance of any incident reported, nor will it be interpreted as registrant agreement with the particular rating assigned. The sole purpose of the rating is for the Agency to quickly categorize the nature and scope of the adverse effect being alleged in order to direct the information to the proper reviewers within the Agency.

The Agency offers the following response to the significant comments received on the issue of incident reporting:

A large number of commenters argued that the Proposed Rule would result in the submission of much information of dubious value that would overwhelm Agency review resources. The Agency shares the commenters’ concern that section 6(a)(2) information be properly managed and that the most important submittals not get lost. The Agency does not believe (as many of the commenters

seem to imply) that the appropriate response is to exempt most incident information from reporting requirements. Instead, the Agency has clarified the summarization requirement in order to both ease the reporting burden on registrants and make the incoming information easier to manage. The Agency also hopes to develop more sophisticated and efficient reporting methods that will make incident reports more consistent, more manageable through automated methods, and correspondingly easier to assess. EPA also expects to use the authority in §159.155 to reduce the number of certain types of repetitive reports.

A few commenters argued that a requirement to report unsubstantiated and uninvestigated incidents is unreasonable, excessively burdensome, and excessively expensive. Many registrants, however, routinely receive incident reports or consumer complaints and already have procedures for gathering and evaluating such reports. Keeping the Agency informed of these reports should not impose a significant additional burden.

The Agency appreciates that the threshold for reporting incidents is far less than conclusive assurance that a reported toxic effect was caused by reported pesticide exposure, and expects that its regulatory decisions will be based upon an appropriate evaluation of all the relevant information available to the Agency. The Agency understands that with the elimination of the provision that called for registrant judgment as to

whether there is a cause and effect relationship between reported exposure and a reported toxic effect, registrants are being directed to report information with which they may disagree. Regulatory decisions will take into account the quality and reliability of any information received. The Agency neither presumes the validity of incident reports nor views such reports as admissions against interest by the submitter.

A number of commenters suggested that the reporting criteria be narrowed so that only additional or new unreasonable adverse effects are reported to the Agency, and that registrants should not be required to report incidents involving effects anticipated or warned about on pesticide labels. To the extent that the commenters are suggesting that additional reports of previously understood effects ought not to be reported, the Agency strongly disagrees. The frequency of occurrence of an adverse effect is extremely important information to pesticide decision-making. The Agency also generally disagrees that incidents involving effects warned about on labels should not be reported. Such incidents can provide important information about the adequacy of label warnings and whether additional steps need to be taken to provide the desired protection.

Similarly, the Agency has a responsibility to consider misuse of pesticides as a factor in determining whether a product is adequately labeled, or should be registered at all. If misuse

incidents involving non-target organisms were exempted, as the Proposed Rule would have provided, potentially significant information for recognizing problem pesticides could be lost. Therefore the Agency has eliminated that proposed exemption.

One commenter suggested that the rule include a provision exempting from reporting incidents involving non-labeled pests. The Agency agrees, and has added such a provision in the Final Rule. Incidents involving toxic effects to non-labeled pests that are similar in kind to pests on the label (e.g., insects or weeds) need not be reported. However, if an event involves a toxic effect to an unrelated pest (e.g., birds or mammals, even if regarded as pests) the incident must be reported.

M. Section 159.188 - Failure of Performance Information

Section 6(a)(2) requires the submission of information concerning unreasonable adverse effects on the environment. The term "unreasonable adverse effects" is statutorily described as a risk/benefit balance. Thus, although section 6(a)(2) reporting has always been focused upon the risks posed by pesticide use, the statutory language includes within its scope information concerning the benefits of pesticide use.

In its 1979 Policy Statement, the Agency announced that it would consider it an actionable violation of section 6(a)(2) to

fail to report information that a pesticide may not have performed efficaciously when used against organisms which pose a potential threat to public health. At that time, the Agency essentially exempted from reporting all failure of efficacy information involving pesticides used against organisms that did not pose a potential threat to human health.

The provision in the 1992 Proposed Rule involving the reporting of failure of performance information required that such information be reported in three circumstances:

1. Information concerning incidents in which a pesticide allegedly failed to perform as claimed against target organisms which, if not controlled, might pose an immediate risk to human health and the registrant has been provided with sufficient information to investigate the allegation and was unable to establish that the reported failure of performance did not occur.

2. Information concerning a series of three or more incidents occurring within 10 years involving allegations that the pesticide did not perform as claimed against target organisms which, if not controlled, might pose a risk to human health and the registrant has been provided with sufficient information to investigate the allegations and was unable to establish that the reported failures of performance did not occur; or information

concerning studies demonstrating that the pesticide may not perform in accordance with any public health claims.

3. Information concerning a series of three or more incidents occurring within 10 years involving allegations that a pesticide that has been the subject of a special review or cancellation or suspension proceeding pursuant to sections 6(b) or 6(c) of FIFRA failed to perform as claimed, or showed a reduction in efficacy, involving a use that was a subject of the special review or suspension or cancellation proceeding.

The Agency received a large number of comments addressing this provision of the Proposed Rule. Some commenters objected to the scope of the provision because it did not require the submission of all efficacy failure information. Other commenters objected to the requirement to submit any failure of efficacy information. Many commenters objected to any requirement to submit consumer complaints that a product might not have worked as effectively as the consumer would have desired, especially in the context of household use products. A number of commenters asked for clarification of many of the provisions of the Proposed Rule, including the differentiation between uses that might pose an immediate risk to human health and uses which might only pose a risk to human health.

The Agency has decided to modify the provisions of this section in the Final Rule. The Final Rule now requires the submission of information concerning failure of efficacy in the following situations:

1. Information concerning incidents involving the failure of a pesticide to perform as claimed against target microorganisms which, if uncontrolled, might pose a threat to human health if the pesticide's function is not a residential use and the registrant has or could obtain information concerning where the incident occurred, the pesticide or product involved, and the name of a person to contact regarding the incident; and information concerning any study indicating that a pesticide might not perform as claimed when used to control microorganisms that might pose a risk to human health, including any of the public health antimicrobials identified in 40 CFR 158.

2. For pesticides used for the purpose of controlling animals (including insects) that might cause disease in humans (either directly or as disease vectors), produce toxins that are harmful to humans, or cause direct physical harm to humans, information must be submitted concerning incidents in which the registrant has been informed by a municipal, state, or federal public health official that the product may not have performed as claimed and the registrant has or could obtain sufficient information concerning where the incident occurred, the pesticide

or product involved, and the name of a person to contact regarding the incident; and information must be submitted concerning studies that indicate that the pesticide may not perform as claimed when used to control animals or insects that might pose a risk to human health.

3. Information must be submitted concerning studies involving the failure of a pesticide to perform against a pest as claimed if the performance of the pesticide in the study was less than the performance standard specified in the Pesticide Assessment Guidelines for Product Performance (Subdivision G) or, if no performance standard is specified or suggested in the Guidelines, if the performance of the pesticide was less than or equal to that of an untreated control, and the pesticide label does not warn the user that the pest control failure might occur when the pesticide is used under the conditions in which the failure occurred.

4. Information concerning substantiation of any incident of pest resistance to any pesticide which occurs in actual use according to the label, whether or not the pesticide has any health-related uses, must be submitted. An incident of pest resistance is considered substantiated if the survival of the suspected pesticide-resistant pest was significantly higher than that of a known susceptible pest when both the suspected resistant and susceptible pests were treated with the pesticide

under the same conditions, or biochemical tests or DNA sequencing indicate that a pest has developed resistance to a pesticide. All incidents involving suspected pest resistance to a pesticide must be reported if the incident occurs in the same state or in a state adjacent to a state where a substantiated incident or study has taken place and the incident involves the same pest as the substantiated incident.

The Agency believes these changes will make it easier for registrants to determine what information must be submitted and will provide the Agency with the failure of efficacy information that is most likely to prove useful to the Agency in fulfilling its pesticide regulatory responsibilities under FIFRA. At the same time, the Agency wants to make it clear that it does not at this time want registrants to submit every allegation of failure of product performance.

The provision for submitting failure of performance of public health antimicrobial pesticides requires registrants to submit information concerning all incidents and all studies involving the possible failure of efficacy of any public health use of an antimicrobial pesticide unless the registrant cannot obtain minimal specified information regarding an incident or if the use involved in the efficacy failure is a residential use. The Agency has eliminated the distinction between uses that might pose an immediate risk to human health and uses that might pose a

risk to human health, and is requiring the submission of all reportable incidents rather than a series of three. The Agency is not requiring the submission of incidents arising from residential uses; EPA does not believe that such uses are likely to be important public health uses, and it believes that the people most likely to be reporting such incidents (ordinary consumers instead of trained health professionals) have less expertise than those that are likely to be involved in reporting incidents involving non-residential uses. In reviewing the Proposed Rule, the Agency discovered that it was ambiguous on the subject of whether studies involving efficacy failures of public health pesticides were reportable under section 6(a)(2). The Final Rule makes clear that any study indicating a lack of efficacy of a public health antimicrobial pesticide must be reported to the Agency.

The Agency established a separate provision for the reporting of incidents and studies involving non-antimicrobial public health pesticides. These pesticides include many insecticides, rodenticides, and other pesticides that control living organisms (other than microbial organisms) that pose a potential health risk to humans. Again, the Agency has eliminated the distinction between an immediate risk to public health and a risk to public health. All incidents meeting the provisions of this Final Rule must be reported. In order to avoid the submission of potentially less reliable reports, the

Agency has decided to require the submission of incident allegations only if the allegation has been made by a government employee (at the federal, state, or local level) involved in the public health field. For example, an incident involving efficacy failure of a mosquitocide reported by an employee of a mosquito control district would be reportable under this provision; a similar incident reported to a registrant by a private citizen would not be reportable. As with antimicrobial pesticides, any study indicating a lack of efficacy of a public health non-antimicrobial pesticide must be reported to the Agency.

For uses of pesticides other than public health uses, the Agency is not requiring the reporting of information concerning incidents where a product is asserted not to have performed in accordance with label claims. The Agency is, however, requiring the submission of studies that indicate that a pesticide's performance failed to meet the guidelines established by the Agency for product performance or, in the absence of a performance guideline, failed to achieve greater pest control than occurred without any pesticide use. Such studies are likely to have greater reliability than consumer allegations of lack of performance, and should prove more useful to the Agency in the performance of its regulatory responsibilities.

The Agency has decided not to differentiate in this provision between pesticide uses that were once the subject of a

special review or cancellation or suspension hearing and all other pesticide uses. If the Agency determines that it needs additional information concerning possible failure of performance of any pesticide, including one that was the subject of a special review or cancellation or suspension hearing, the Agency can request that information pursuant to §159.195 of this Final Rule. In addition, if the conclusion of a special review or cancellation or suspension hearing clearly provides (or provided) that the pesticide product was being allowed to remain on the market only because the product was significantly more effective than alternative products, registrants would be obligated to provide information calling into question the continuing efficacy of the product under §159.195.

Finally, the Agency has determined that substantiated information about pest resistance is another area where failure of performance information may assist the Agency in the performance of its regulatory role. The Agency is therefore requiring the submission of information concerning the occurrence of pest resistance under actual conditions of use, where such information meets a defined standard of reliability. In order to track the potential spread of pesticide resistance, after substantiated information has been received concerning pest resistance to a particular pesticide, the Agency is requiring the submission of additional information or reports, even if unsubstantiated, if it involves the same pesticide/pest

combination, and occurs in the same state or in states adjacent to a state where a substantiated incident has been reported.

Several commenters, noting that efficacy against pests is the primary benefit offered by pesticide products, argued that EPA has no authority to require information on efficacy failure (or any other lack of benefits information) under section 6(a)(2). To support this position, one commenter cited the District Court decision in the CSMA case. The Agency appreciates that the court in that case opined that benefits information was outside the scope of section 6(a)(2). However, the Agency believes that the court was clearly incorrect on this point. Section 2(bb) of FIFRA defines unreasonable adverse effects on the environment as including the consideration of information on benefits as well as risks. It is clear under FIFRA that a failure of efficacy of a product could tip the risk/benefit balance in favor of cancellation of a product or specific uses of a product. Under such circumstances, the Agency believes there is no question that failure of efficacy information falls within the statutory scope of material covered by section 6(a)(2).

N. Section 159.195 - Reporting of Other Information

The 1992 Proposed Rule required the submission of information not included within any of the other provisions of the rule if the registrant is not aware of facts which establish

that the information is incorrect and the registrant knows, or should know, that if the information should prove to be correct, EPA would regard the information either alone or in conjunction with other information as having the potential to raise questions about the continued registration of a product or about the appropriate terms and conditions of registration of a product. Similar general provisions have been included in all previous Agency policy statements and interpretations of section 6(a)(2).

In response to a comment, the Agency added one example to the types of information that must be reported under §159.195(a) of this Final Rule. Specifically, the Agency is making it clear that it considers any information which might tend to invalidate in any way a study submitted to the Agency to support a pesticide registration, to be reportable under section 6(a)(2).

The Agency intends to take enforcement action pursuant to this provision only when it believes a registrant clearly should have known that information would have been considered important by the Agency in its evaluation of a pesticide product registration. If a registrant is aware that the registration decision for one of its products was based upon an assumption by the Agency that is called into question by some new piece of information, that information must be provided under this provision if it is not already reportable under some other provision of this Final Rule. In situations where a registrant

is unsure how this provision applies to specific information, the Agency encourages the registrant to seek advice from EPA.

The Agency on occasion may notify a registrant that it considers a particular type of information to be reportable pursuant to section 6(a)(2). Such a notification to the registrant removes any question concerning whether the registrant should know that the Agency considers the information important. In order to eliminate any possible confusion on this point, EPA has added a specific provision spelling out a registrant's obligation when it is informed that the Agency desires the submission of specific information pursuant to section 6(a)(2).

III. REGULATORY REVIEW REQUIREMENTS

A. Executive Order 12866; Unfunded Mandates Reform Act

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether a regulatory action is "significant" and therefore subject to all the requirements of the Executive Order. Under section 3(f), the order defines "significant" as those actions likely to lead to: (1) An annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities; (2) a serious

inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees or loan programs; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of this Executive Order, EPA has determined that this rule is not "significant" because it will have a very minor economic impact on pesticide registrants, and no impact on any other sector of the economy, or on any other government entities, programs or policies. This Final Rule is consistent with the purposes of FIFRA, and does not conflict with any other statutory mandate or with the principles of the Executive Order.

This determination also satisfies the requirement of the Unfunded Mandates Reform Act of 1995 (UMRA), Pub.L. 104-4, requiring Federal agencies to assess the effects of their regulatory actions on State, local and tribal governments and the private sector. This rule contains no Federal mandate affecting State, local or tribal governments. The aggregate annual impact on the private sector is estimated to be about $1,000,000. The basis for EPA’s determination is contained in the Information Collection Request for this rule (see section D, below).

B. Referral to the Secretary of Agriculture and the Scientific Advisory Panel

In accordance with section 25 of FIFRA, a copy of this Final Rule was provided to the Secretary of the Department of Agriculture (USDA), the FIFRA Scientific Advisory Panel (SAP), the Committee on Agriculture, Nutrition and Forestry of the U.S. Senate, and the Committee on Agriculture of the U.S. House of Representatives. If the Secretary or the Panel comments in writing within 15 days of receipt of the rule, EPA will publish any comments received, and EPA's responses, in the Notice of Final Rulemaking. Neither USDA nor the SAP commented on the proposed rule.

C. Regulatory Flexibility Act

This rule was reviewed under the provisions of the Regulatory Flexibility Act, and it was determined that the rule would not have a significant adverse impact on a substantial number of small entities. EPA estimates that this regulation will impose a total cost of about one million dollars (or less) distributed among approximately 2,500 pesticide registrants. Since only a fraction of these are small entities, the number of small entities affected and the cost imposed on them is substantially less than the total. I therefore certify that this

final rule does not require a separate Regulatory Impact Analysis under the Regulatory Flexibility Act.

D. Paperwork Reduction Act

Current information collection activities relating to section 6(a)(2) are conducted under an Information Collection Request (ICR No. 1204) approved by the Office of Management and Budget (OMB No. 2070-0039) which expires November 30, 1996. An amendment to this ICR to cover the information collection requirements in this final rule has been submitted to OMB under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. A copy of the amended ICR may be obtained from Sandy Farmer, OPPE Regulatory Information Division, U. S. Environmental Protection Agency (2136), 401 M St., SW., Washington, DC 20460, or by calling (202) 260-2740.

The annual reporting burden for this collection of information is estimated to be 5.9 hours per response involving submission of scientific studies, and 2.3 hours per response for submission of incident reports. These estimates include the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, and disclosing and providing information; adjust the existing ways to comply with

any previously applicable instructions and requirements; train personnel to respond to a collection of information; search existing data sources; complete and review the collection of information; and transmit or otherwise disclose the information. No person is required to respond to a collection of information unless it displays a currently valid OMB control number. OMB control numbers for EPA regulations are listed in 40 CFR part 9.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, OPPE Regulatory Information Division; U.S. Environmental Protection Agency (2136), 401 M St., SW., Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington DC 20503, marked "Attention: Desk Officer for EPA." Include the ICR number in any correspondence.

List of Subjects in 40 CFR Parts 153 and 159

Environmental protection, Pesticides and pests, Policy statements, Reporting and recordkeeping requirements.

Dated: _____.

Administrator.

Therefore, 40 CFR Chapter I is amended as follows:

PART 153 [AMENDED]

1. In Part 153:

a. The authority citation for part 153 continues to read as follows:

Authority: 7 U.S.C. 136 - 136y.

SUBPART D [REMOVED AND RESERVED]

b. By removing subpart D, consisting of §§ 153.61 through 153.79, and designating subpart D as "[Reserved]."

2. By adding new part 159 consisting of Subparts A, B, and C, which are reserved, and Subpart D to read as follows:

PART 159 -- STATEMENTS OF POLICIES AND INTERPRETATIONS

Subparts A -- C [Reserved]

Subpart D -- Reporting Requirements for Risk/Benefit Information

Sec.

159.152 What the law requires of registrants.

159.153 Definitions.

159.155 When information must be submitted.
159.156 How information must be submitted.
159.158 What information must be submitted.
159.159 Information obtained before promulgation of the rule.
159.160 Exception relating to former registrants.
159.165 Toxicological and ecological studies.
159.167 Discontinued studies.
159.170 Human epidemiological and exposure studies.
159.178 Information on pesticides in or on food, feed, or water.
159.179 Metabolites, degradates, contaminants, and impurities.
159.184 Toxic or adverse effect incident reports.
159.188 Failure of performance information.
159.195 Reporting of other information.

Authority: 7 U.S.C. 136 - 136y

Subparts A--C [Reserved]

Subpart D--Reporting Requirements for Risk/Benefit Information

§ 159.152 What the law requires of registrants.

(a) Section 6(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) states: "If at any time after the registration of a pesticide the registrant has additional factual

information regarding unreasonable adverse effects on the environment of the pesticide, he shall submit such information to the Administrator."

(b) Section 152.50(f)(3) of this chapter requires applicants to submit, as part of an application for registration, all information about a pesticide that would have to be supplied pursuant to section 6(a)(2) if the pesticide were registered.

(c) Compliance with this part will satisfy a registrant's obligations to submit additional information pursuant to section 6(a)(2) and will satisfy an applicant's obligation to submit additional information pursuant to §152.50(f)(3) of this chapter.

§ 159.153 Definitions.

(a) For the purposes of reporting information pursuant to FIFRA section 6(a)(2), the definitions set forth in FIFRA section 2 and in § 152 of this chapter apply to this part unless superseded by a definition in paragraph (b) of this section.

(b) For purposes of reporting information pursuant to FIFRA section 6(a)(2), the following definitions apply only to this part:

"Established level" means a tolerance, temporary tolerance, food additive regulation, action level, or other limitation on residues imposed by law, regulation, or other authority.

"Formal Review" means Special Review, Rebuttable Presumption Against Registration (RPAR), FIFRA section 6(c) suspension proceeding, or FIFRA section 6(b) cancellation proceeding, whether completed or not.

"Maximum contaminant level (MCL)" means the maximum permissible level, established by EPA, for a contaminant in water which is delivered to any user of a public water system.

"Non-target organism" means any organism for which pesticidal control was either not intended or not legally permitted by application of a pesticide.

"Pesticide" means a pesticide product which is or was registered by EPA, and each active ingredient, inert ingredient, impurity, metabolite, contaminant or degradate contained in, or derived from, such pesticide product.

"Qualified expert" means one who, by virtue of his or her knowledge, skill, experience, training, or education could be qualified by a court as an expert to testify on issues related to

the subject matter on which he or she renders a conclusion or opinion.

"Registrant" includes any person who holds, or ever held, a registration for a pesticide product issued under FIFRA section 3 or 24(c), including any employee or agent of such a person; provided that any employee or agent who is not expected to perform any activities related to the development, testing, manufacturing, sale or registration of a pesticide, and who could not reasonably be expected to come into possession of information that is otherwise reportable under this part, shall not be considered a registrant for purposes of this part; and provided further that information possessed by an agent shall only be considered to be possessed by a registrant if the agent acquired such information while acting for the registrant.

"Similar species" means two or more species belonging to the same general taxonomic groups: The general taxonomic groups for purposes of this requirement are: mammals, birds, reptiles, amphibians, fish, aquatic invertebrates, insects, arachnids, aquatic plants (including macrophyte, floating, and submerged plants), and terrestrial (all non-aquatic) plants.

"Water reference level" means the level specified in paragraph (1) or (2) below, whichever is lower.

(1) Ten percent of the maximum contaminant level (MCL) established by EPA, or if no MCL has been established by EPA, 10 percent of the most recent draft or final long-term health advisory level (HAL) established by EPA, or if EPA has not published or proposed an MCL or HAL, the lowest detectable amount of the pesticide.

(2) The Ambient Water Quality Criteria for the Protection of Aquatic Life, established by EPA pursuant to § 304(a) of the Clean Water Act.

§ 159.155 When information must be submitted.

(a) Reportable information must be received by EPA not later than the 30th calendar day after the registrant first possesses or knows of the reportable information. EPA may, in its discretion, notify a registrant in writing of a different reporting period that will apply to specific types of reportable information or eliminate reporting requirements entirely. Such notification supersedes the otherwise-applicable 30-day reporting requirement.

(b) For purposes of this part a registrant possesses or knows of information at the time any officer, employee, agent, or

other person acting for the registrant first comes into possession of, or knows of, such information.

§ 159.156 How information must be submitted.

A submission under FIFRA section 6(a)(2) must be delivered as specified in either paragraph (a) or (b):

(a) Be mailed by certified or registered mail to the following address, or such other address as the Agency may subsequently specify in writing:

Document Processing Desk -- 6(a)(2)
Office of Pesticide Programs - 7504C
U.S. Environmental Protection Agency,
401 M St., SW.,
Washington, D.C. 20460.

(b) Be delivered in person or by courier service or by such other methods as the Agency deems appropriate to the following address, or to such other address as the Agency may subsequently specify in writing:

Document Processing Desk -- 6(a)(2)
Office of Pesticide Programs
Room 266A, Crystal Mall #2

1921 Jefferson Davis Highway
Arlington, Virginia 22202.

(c) Include a cover letter which contains information requested in paragraphs (d) and (e) of this section, and a prominent statement that the information is being submitted in accordance with FIFRA section 6(a)(2).

(d) Contain the name of the submitter, company name and number, date of transmittal to EPA, the type of study or incident being reported under §§ 159.165 through 159.195, and a statement of why the information is considered reportable under this part.

(e) Identify the substance tested or otherwise covered by the information (including, if known, the EPA registration number(s) to which the information pertains, and if known, the CAS Registry Number).

(f) In reporting incidents, provide the data listed in §159.184, to the extent such information is available.

(g) In submitting scientific studies, follow the procedures set forth in § 158.32 of this chapter.

(h) If the information is part of a larger package being submitted in order to comply with another provision of FIFRA

(e.g., sections 3(c)(2)(B), 4(e)(1)(E)), identify in the transmittal the individual studies being submitted under this part.

(i) If a claim of confidentiality is made for information relating to any part of a study or incident report contained in the submission, follow the procedures set forth in § 158.33 of this chapter regarding the identification and segregation of information claimed to be confidential.

(j) If a submission includes a study subject to the flagging requirements of § 158.34 of this chapter, comply with the requirements of that section, and identify it as 6(a)(2) information in the transmittal.

(k) If a submission is a follow-up to an earlier study or incident report submitted to EPA, the transmittal must state that fact, and must cite the earlier submission, as follows:

(1) If the earlier submission was a study to which EPA assigned a Master Record Identifier number (MRID), cite the MRID;

(2) If the previous submission was an incident report to which no MRID number was assigned, cite the date of the incident.

§ 159.158 What information must be submitted.

(a) General. Information which is reportable under this part must be submitted if the registrant possesses or knows of the information, and the information is relevant to the assessment of the risks or benefits of one or more specific pesticide registrations currently or formerly held by the registrant, regardless of whether the information directly involved such registered pesticide(s). Information relevant to the assessment of the risks or benefits also includes conclusion(s) or opinion(s) rendered by a person:

(1) Who was employed or retained (directly or indirectly) by the registrant; or,

(2) From whom the registrant requested the opinion(s) or conclusion(s) in question; or,

(3) Who is a qualified expert as described in §159.153(b).

(b) Publications. Scientific articles pertaining to epidemiological studies or incident reports describing potential adverse effects of pesticides must be submitted.

(c) Exceptions. (1) Clearly erroneous information. Information need not be submitted if before the date on which the registrant must submit such information:

(i) The registrant discovers that any analysis, conclusion, or opinion was predicated on data that were erroneously generated, recorded, or transmitted, or on computational errors.

(ii) Every author of each such analysis, conclusion, or opinion, or as many authors as can be contacted through the use of reasonable diligence, has acknowledged in writing that the analysis, conclusion, or opinion was improper and has either corrected the original analysis, conclusion, or opinion accordingly, or provided an explanation as to why it cannot be corrected.

(iii) As a result of the correction, the information is no longer required to be reported under FIFRA section 6(a)(2), or if no correction was possible, the authors agree that the original analysis, conclusion or opinion has no scientific validity.

(2) Previously submitted information. Information regarding an incident, study, or other occurrence need not be submitted if before the date on which the registrant must submit such information, the registrant is aware that the reportable

information concerning that incident, study, or other occurrence is contained completely in one of the following:

(i) Documents officially logged in by the EPA Office of Pesticide Programs.

(ii) EPA publications, EPA hearing records, or publications cited in EPA Federal Register notices.

(iii) Any other documents which are contained in the official files and records of the EPA Office of Pesticide Programs.

(3) Publications. A published article or report containing information otherwise reportable under this part need not be submitted if it fits into the categories described in paragraphs(c)(3)(i) or (c)(3)(ii) of this section.

(i) Any scientific article or publication which has been abstracted in Biological Abstracts, Chemical Abstracts, Index Medicus, or Pesticides Abstracts, if the abstract in question clearly identified the active ingredient or the registered pesticide(s) to which the information pertains. (Otherwise reportable information received by or known to the registrant prior to publication of an abstract concerning the information

must be reported and may not be withheld pending such publication).

(ii) Reports or publications which have been made available to the public by any of the following Federal agencies: Centers for Disease Control and Prevention, Consumer Products Safety Commission, Department of Agriculture, Department of the Interior, Food and Drug Administration or any other agency or institute affiliated with the Department of Health and Human Services. (Otherwise reportable information concerning research which was performed, sponsored, or funded by the registrant which may also appear in forthcoming Government report of publication must be reported and may not be withheld pending publication).

§ 159.159 Information obtained before promulgation of the rule.

(a) Notwithstanding any other provision of this part, information held by registrants on [insert date 270 days after date of publication in the Federal Register] which has not been previously submitted to the Agency, but which is reportable under the terms of this part, needs to be submitted to the Agency if it meets any of the following criteria.

(1) Information is otherwise reportable under §§ 159.165, 159.170, 159.179 or 159.188, and the study was concluded on or after [insert date 5 years before effective date of this rule].

(2) Information is otherwise reportable under § 159.184, and pertains to an incident that is alleged to have involved:

(i) A fatality or hospitalization of a human being.

(ii) A fatality of a domestic animal.

(iii) A fatality of a non-target organism.

(3) Submission of the information is requested by the Agency pursuant to § 159.195(b).

(b) If a registrant possesses information required to be submitted by paragraphs (a)(1) or (a)(2) of this section, the registrant must either:

(1) Submit the information pursuant to all applicable provisions of this Part on or before [insert date 1 year after the effective date of this rule].

(2) Submit on or before [insert date 1 year after the effective date of this rule] in accordance with § 159.156(c), (d), and (e) an inventory of the studies and/or incidents that meet the requirements of paragraphs (a)(1) and (a)(2) of this section. Such an inventory must include a list of any individual studies meeting the requirements of paragraph (a)(1) of this

section, including identification of the type of study, and for incidents that are reportable, the separate number of incidents that meet the requirements of paragraphs (a)(2)(i), (a)(2)(ii), and (a)(2)(iii) of this section, and for each type of incident, the total numbers of fatalities or hospitalizations involved.

(c) If a registrant possesses information required to be submitted by paragraph (a)(3) of this section, the information must be submitted in accordance with any schedule contained in the Agency’s request for the information.

§ 159.160 Exception relating to former registrants.

Notwithstanding any other provision of this part, a registrant is not required to report information that would otherwise be reportable under this part if:

(a) The information is first obtained by the person more than 1 year after the date on which the person ceased to hold the registration of the product to which the information pertains, and the person holds no active pesticide registrations, or for some other reason cannot reasonably be expected to receive information concerning the formerly-registered product.

(b) The information is associated solely with an inert ingredient, contaminant, impurity, metabolite, or degradate

contained in a product, and the information is first obtained by the person more than 3 years after the date upon which the person ceased to hold the registration of the product.

§ 159.165 Toxicological and ecological studies.

Adverse effects information must be submitted as follows:

(a) Toxicological Studies. The results of an incomplete or complete study of the toxicity of a pesticide to humans or other non-target domestic organisms if, relative to all previously submitted studies, they show an adverse effect:

(1) That is in a different organ or tissue of the test organism; or

(2) At a lower dosage, or after a shorter exposure period, or after a shorter latency period; or

(3) At a higher incidence or frequency; or

(4) In a different species, strain, sex, or generation of test organism; or

(5) By a different route of exposure.

(6) Acute oral, acute dermal, acute inhalation or skin and eye irritation studies in which the only change in toxicity is a numerical decrease in the median lethal dose (LD50), median lethal concentration (LC50) or irritation indices, are not reportable under this part unless the results indicate a more restrictive toxicity category for labeling under the criteria of 40 CFR 156.10(h).

(b) Ecological Studies. The results of an incomplete or complete study of the toxicity of a pesticide to terrestrial or aquatic wildlife or plants if, relative to all previously submitted studies, they show an adverse effect:

(1) At levels 50 percent or more lower than previous acute toxicity studies with similar species, including determinations of the median lethal dose (LD50), median lethal concentration (LC50), or median effective concentration (EC50); or

(2) At lower levels in a chronic study than previous studies with similar species; or

(3) In a study with a previously untested species the results indicate the chronic no observed effect level (NOEL) is 10 percent or less of the lowest LC50 or LD50 for a similar species; or

(4) For plants when tested at the maximum label application rate or less, if:

(i) More than 25 percent of terrestrial plants show adverse effects on plant life cycle functions and growth such as germination, emergence, plant vigor, reproduction and yields; or

(ii) More than 50 percent of aquatic plants show adverse effects on plant life cycle functions and growth such as germination, emergence, plant vigor, reproduction and yields.

(c) Results from a study that demonstrates any toxic effect (even if corroborative of information already known to the Agency), must be submitted if the pesticide is or has been the subject of a Formal Review based on that effect within 5 years of the time the results are received. Within 30 calendar days of the publication of a Notice of Commencement of a Formal Review in the FEDERAL REGISTER, all information which has become reportable due to the commencement of the Formal Review must be submitted.

(d) Notwithstanding any other provision of this part, information from an incomplete study that is otherwise reportable pursuant to this section need not be reported prior to completion of the study if the study is intended to be, and subsequently is, completed and submitted within 90 days.

§ 159.167 Discontinued studies.

The fact that a study has been discontinued before the planned termination must be reported to EPA, with the reason for termination, if submission of information concerning the study is, or would have been, required under this part.

§ 159.170 Human epidemiological and exposure studies.

Information must be submitted which concerns any study that a person described in § 159.158(a) has concluded, or might reasonably conclude, shows that a correlation may exist between exposure to a pesticide and observed adverse effects in humans. Information must also be submitted which concerns exposure monitoring studies that indicate higher levels of risk or exposure than would be expected based on previously available reports, data, or exposure estimates. Such information must be submitted regardless of whether the registrant considers any observed correlation or association to be significant.

§ 159.178 Information on pesticides in food, feed or water.

(a) Food and Feed. Information must be submitted if it arguably shows that the pesticide is present on food or feed at a level in excess of established levels, except that information on

excess residues resulting solely from studies conducted under authority of FIFRA section 5 need not be submitted.

(b) Water. (1) Information must be submitted if it arguably shows that a pesticide is present above the water reference level in:

(i) Waters of the United States , as defined in § 122.2 of this chapter, except paragraph (d) of § 122.2; or

(ii) Ground water; or

(iii) Finished drinking water.

(2) If the lowest detectable amount of the pesticide is reported, the detection limit must also be reported.

(3) Information need not be submitted regarding the detection of a pesticide in waters of the United States or finished drinking water under conditions specified in paragraphs (b)(3)(I) or (b)(3)(ii) of this section.

(i) The pesticide is registered for use in finished drinking water or surface water and the amount detected does not exceed the amounts reported by a registrant in its application for

registration, as resulting in those waters from legal applications of the pesticide.

(ii) The substance detected is an inert ingredient, or a metabolite, degradate, contaminant or impurity, unless EPA has established or proposed a maximum contaminant level (MCL) or health advisory level (HAL) for that substance, or has estimated a health advisory level based on an established reference dose (RfD) for that substance, and notified registrants of that level.

§ 159.179 Metabolites, degradates, contaminants, and impurities.

Information which shows the existence of any substance which appears to be a pesticide, as defined in this part, must be submitted if:

(a) The substance may occur or be present under conditions of use of the pesticide product, and either:

(1) The existence of the substance or the association of the substance with the pesticide product has not previously been reported to EPA.

(2) The substance has been previously reported, but it is detected at levels higher than any previously reported.

(b) In addition to the requirements of paragraphs (a)(1) and (a)(2) of this section, information concerning a substance is reportable only if it meets one or more of the conditions contained in paragraphs (b)(1) or (b)(2) of this section.

(1) Any person described in § 159.158(a) has concluded that the substance may pose a toxicological or ecological risk based on any of the following:

(i) The physical or chemical properties of the substance.

(ii) Data regarding structurally analogous chemicals.

(iii) Data regarding chemical reactivity of the substance and structurally analogous substances.

(iv) Data on the substance.

(2) The registrant has concluded, or has been advised by any person described in § 159.158(a) that the substance, or analogous chemicals, may have any experimentally determined half-life greater than 3 weeks as shown from laboratory aerobic soil metabolism studies or field dissipation studies, or may have any

experimentally determined resistance to hydrolytic degradation, or photolytic degradation on soil or in water, under any conditions, resulting in degradation of less than 10 percent in a 30-day period.

§159.184 Toxic or adverse effect incident reports.

(a) Information about incidents affecting humans or other non-target organisms must be submitted if:

(1) The registrant is aware, or has been informed that a person or non-target organism may have been exposed to a pesticide.

(2) The registrant is aware, or has been informed that the person or non-target organism may have suffered or may suffer a toxic or adverse effect.

(b) Exceptions. Information regarding an incident need not be submitted if:

(1) The registrant is aware of facts which clearly establish that the reported toxic effect, or reported exposure, did not or will not occur.

(2) The registrant has been notified in writing by the Agency that the reporting requirement has been waived for this incident or category of incidents, and the registrant has not been notified in writing by the Agency that the waiver is rescinded.

(3) It concerns a non-lethal toxic effect to non-target plants, which were at the use site at the time the pesticide was applied, if the label provides adequate notice of such a risk.

(4) It concerns non-lethal phytotoxicity to the treated crop if the label provides an adequate notice of such a risk.

(5) It concerns a toxic effect to pests not specified on the label, provided that such pests are similar to pests specified on the label.

(c) Required information on individual incidents. To the extent that the registrant has any of the information listed in paragraphs (c)(1) through (c)(4) of this section, the registrant must supply the information on each pesticide incident that meets the requirements outlined in paragraph(a) of this section. In the future, the Agency may by notice specify a format for such submissions. The Administrative, Pesticide, Circumstance and Incident Type(s) information must be reported for individual incidents, unless EPA has granted permission in writing to

aggregate reports. The registrant must also provide one or more Adverse Effects Category labels for each incident as set forth in paragraph (c)(5) of this section, depending on the applicability of the categories listed below. The criteria listed should be used in assigning a label. The separate Incident Types that have a choice of label categories are limited to those involving human beings, domestic animals, fish and wildlife, plants, and water contamination. There are no criteria for labeling of adverse effects for product defects, pest resistance or property damage. However, if one of these is applicable, it should be included in the category label. For example, an incident which allegedly caused serious but non-fatal effects to human beings and domestic animals resulting from a container failure might be labeled "H-B: D-B: product defect". When a single incident involves multiple pesticides, the registrant need only report on their specific product. However, if a single incident involves more than one type of non-target organism -- for example, both humans and domestic animals are involved -- all appropriate available information dealing with each of the victims must also be reported. Informational items below are grouped by sections for ease in reporting pesticide incidents.

1. Administrative. If the registrant has any of the following information it must be submitted.

(i) Incident type.

(ii) The adverse effect category.

(iii) Name of reporter, address, and telephone number.

(iv) Name, address, and telephone number of contact person (if different than reporter);

(v) Incident report status (e.g., new or update); if update, include the date of occurrence.

(vi) Date registrant became aware of the incident.

(vii) Date of incident (if appropriate, list start and end dates).

(viii) Location of incident (city, county and state).

(ix) Is incident part of a larger study.

(x) Source if different from reporting registrant.

(2) Pesticide. If the registrant has any of the following information, it must be submitted.

(i) Product name.

(ii) Active ingredient(s).

(iii) EPA Registration Number.

(iv) Diluted for use, or concentrate;

(v) Formulation, if known.

(vi) List the same information under paragraphs (c)(2)(I) through (c)(2)(v) for other pesticides that may have contributed to this incident.

(3) Circumstance. If the registrant has any of the following information, it must be submitted.

(i) Evidence the label directions were not followed (e.g., yes, no, unknown).

(ii) How exposed (e.g., spill, spray drift, equipment failure, runoff, etc.).

(iii) Situation (e.g., household use, mixing/loading, application, reentry, disposal, transportation, other (describe).

(iv) Use site (e.g., home, yard, commercial turf, agricultural (specify crop), industrial, building/office, school, nursery, greenhouse, pond/lake/stream, well, forest/woods, other.

(v) Applicator certified (yes, no, unknown).

(vi) A brief description of the circumstances of the incident.

(4) Incident Type. If the registrant has any of the following information, it must be submitted.

(i) If Human: (*a*) Route of exposure (skin, eye, respiratory, oral).

(*b*) List signs/symptoms/adverse effects.

(*c*) If laboratory tests were performed, list name of test(s) and results.

(*d*) If available, submit laboratory report(s).

(*e*) Time between exposure and onset of symptoms.

(*f*) Was adverse effect the result of suicide/homicide or attempted suicide/homicide.

(*g*) Type of medical care sought, (e.g., none, Poison Control Center, hospital emergency department, hospital inpatient, private physician, clinic, other).

(*h*) Demographics (sex, age, race, occupation).

(*i*) If female, pregnant?

(*j*) Exposure data: amount of pesticide; duration of exposure; weight of victim.

(*k*) Was exposure occupational; days lost due to illness.

(*l*) Was protective clothing worn (specify).

(ii) If Domestic Animal. (*a*) Type of animal (e.g., livestock, poultry, bird, fish, household pet e.g., dog/cat etc.).

(*b*) List signs/symptoms/adverse effects.

(*c)* Breed/Species (name and number affected, per adverse effect).

(*d*) Route of exposure (e.g., skin, eye, respiratory, oral).

(*e*) Time between exposure and onset of symptoms.

(*f*) If laboratory test(s) performed, list name of tests and results.

(*g*) If available, submit laboratory report(s).

(iii) If Fish, Wildlife, Plants or Other Non-Target Organisms. (*a*)List species affected, and number of individuals per species.

(*b*) List symptoms or adverse effects.

(*c*) Magnitude of the effect (e.g., miles of streams, square area of terrestrial habitat).

(*d*) Pesticide application rate, intended use site (e.g., corn, turf), and method of application.

(*e*) Description of the habitat and the circumstances under which the incident occurred.

(*f*) If plant, type of plant life (i.e., crop, forest, orchard, home garden, ornamental, forage).

(*g*) Formulation of pesticide if not indicated by brand name (granular, flowable).

(*h*) Distance from treatment site.

(i) If laboratory test(s) performed, list name of test(s) and results.

(*j*) If available, submit laboratory report(s).

(iv) If Surface Water. (*a*) If raw water samples, water bodies sampled and approximate locations in each water body.

(*b*) If raw water samples, proximity of sampling locations to drinking water supply intakes and identities of systems supplied.

(*c*) If finished water samples, water supply systems sampled.

(*d*) If finished water samples, percent surface water source by specific surface water sources to water supply system(s).

(*e*) Sample type (grab, composite).

(*f*) Sampling times/frequency.

(*g*) Pesticides and degradates analyzed for and their detection limits.

(*h*) Method of analysis.

(v) If Ground Water. (*a*) Pesticide and degradates analyzed for and the analytical methods and detection limits.

(*b*) Sample date.

(c) Amount pesticide applied (lbs-ai/acre).

(*d*) Date of last application.

(*e*) Depth to water.

(*f*) Latitude/longitude.

(*g*) Soil series and texture (sand/silt/clay).

(*h*) Frequency of applications per year.

(*i*) Aquifer description (confined/unconfined).

(*j*) Method of application.

(*k*) Years pesticide used.

(*l*) Well use and well identifier.

(*m*) Screened interval.

(*n*) Altitude.

(*o*) Annual cumulative rainfall (inches).

(*p*) Maximum rainfall and date.

(*q*) Cumulative irrigation (inches).

(*r*) High/low annual mean temperatures.

(*s*) Evapotranspiration.

(*t*) Hydrologic group.

(*u*) Mineralogy.

(*v*) Hydraulic conductivity.

(*w*) pH.

(*x*) Organic matter or organic carbon (percent).

(*y*) Bulk density.

(vi) If property damage. (*a*) Provide description.

(*b*) [Reserved].

(vii) If product defect. (*a*) Type of product defect (formulation, contamination, corrosion, label printing error, specify other).

(*b*) Provide description.

(viii) If pest resistance. (*a*) Pest.

(*b*) Crop.

(c) Substantiation method.

(*d*) Substantiation test results.

(*e*) Laboratory reports.

(*f*) Additional pesticides (if substantiated resistance to multiple pesticides).

(5) Adverse effect categories and labels. (i) Humans. If an alleged effect involves a human, provide the appropriate 2-letter notation based upon the following categories:

(*a*) H-A: If the person died.

(*b*) H-B: If the person exhibited symptoms which may have been life-threatening or resulted in residual disability.

(c) H-C: If the person exhibited symptoms which are more pronounced, more prolonged or more of a systemic nature than minor symptoms. Usually some form of treatment is or would have been indicated to treat the person. Symptoms were not life threatening and the person has returned to his/her pre-exposure state of health with no additional residual disability.

(*d*) H-D: If the person exhibited some symptoms, but they were minimally bothersome. The symptoms resolved

rapidly and usually involve skin, eye or respiratory irritation.

(*e*) H-E: If the incident alleges unexpected exposure to a pesticide, and no symptoms have yet been observed.

(ii) Domestic animals. If an alleged effect involves a domestic animal, provide the appropriate 2-letter notation based upon the following categories:

(*a*) D-A: If the domestic animal died.

(*b*) D-B: If the domestic animal exhibited symptoms which may have been life-threatening or resulted in residual disability.

(*c*) D-C: If the domestic animal exhibited symptoms which are more pronounced, more prolonged or more of a systemic nature than minor symptoms. Usually some form of treatment is or would have been indicated to treat the animal. Symptoms were not life threatening and the domestic animal has returned to its pre-exposure state of health with no additional residual disability.

(*d*) D-D: If the domestic animal exhibited some symptoms, but they were minimally bothersome. The symptoms resolved rapidly and usually involve skin, eye or respiratory irritation.

(*e*) D-E: If the incident alleges unexpected pesticide exposure, and no symptoms have yet been observed.

(iii) Fish or wildlife. If an alleged effect involves fish or wildlife, label the incident **W-A** if any of the criteria listed in paragraphs (c)(5)(iii)(*a*) through (c)(5)(iii)(*g*) of this section are met, or **W-B** if none of the criteria are met:

(*a*) Involves any incident caused by a pesticide currently in Formal Review for ecological concerns;

(*b*) Fish: Affected 1,000 or more individuals of a schooling species or 50 or more individuals of a non-schooling species;

(*c*) Birds: Affected 200 or more individuals of a flocking species, or 50 or more individuals of a songbird species, or 5 or more individuals of a predatory species;

(*d*) Mammals, Reptiles, Amphibians: Affected 50 or more individuals of a relatively common or herding species or 5 or more individuals of a rare or solitary species;

(*e*) Involves effects to, or illegal pesticide treatment (misuse) of a substantial tract of habitat (greater than or equal to 10 acres, terrestrial or aquatic);

(*f*) Involves a major spill or discharge (greater than or equal to 5,000 gallons) of a pesticide;

(*g*) Involves adverse effects caused by a pesticide, to Federally listed endangered or threatened species.

(iv) Plants. If an alleged effect involves damage to plants, label the incident **P-A** if the single criterion listed in paragraph (c)(5)(iv)(*a*) of this section is met, or **P-B** if the criterion is not met:

(*a*) The effect is alleged to have occurred on more than 45 percent of the acreage on which the pesticide was used by the person reporting the incident.

(*b*) [Reserved]

(v) Other non-target organisms. If an alleged effect involves damage to non-target organisms other than fish, wildlife or plants (for example, beneficial insects), label the incident **ONT**.

(vi) Water contamination. If a pesticide is alleged to have been detected in groundwater, surface water or finished

drinking water, label the incident in accordance with the following criteria:

(*a*) **G-a**: If the pesticide was detected at levels greater than the maximum contaminant level (MCL) or health advisory level (HAL) or an applicable criterion for ambient water quality.

(*b*) **G-B**: If the pesticide was detected at levels greater than 10 percent of the MCL, HAL or a criterion for ambient water quality but does not exceed the MCL or other applicable level.

(c) **G-C**: If the pesticide was detected at levels less than 10 percent of the MCL, HAL, or other applicable level, or there is no established level of concern.

(vii) Property damage or product defect. If an incident involves alleged property damage or product defect, the applicable term(s) shall be included along with any other applicable effect category label; for example, "H-B: product defect".

(viii) Pest resistance. If an incident involves suspected or substantiated pest resistance, label the incident **PR**.

§ 159.188 Failure of performance information.

(a) Microorganisms that pose a risk to human health. Information must be submitted which concerns either incidents described in paragraph (a)(1) of this section or a study described in paragraph (a)(2) of this section:

(1) Information which concerns an incident in which:

(i) The registrant has been informed that a pesticide product may not have performed as claimed against target microorganisms.

(ii) The possible failures of the pesticide to perform as claimed involved the use against microorganisms which may pose a risk to human health.

(iii) The pesticide product’s use site is other than residential.

(iv) The registrant has or could obtain information concerning where the incident occurred, the pesticide or product involved, and the name of a person to contact regarding the incident.

(2) A study which indicates that the pesticide may not perform in accordance with one or more claims made by the registrant regarding uses intended for control of microorganisms that may pose a risk to human health, including any of the public health antimicrobials identified in part 158 of this chapter.

(b) Animals that pose a risk to human health. Any animal (including insects) poses a risk to human health if it may cause disease in humans, either directly or as a disease vector; produce toxins that are harmful to humans; or cause direct physical harm to humans. Information must be submitted which concerns either incidents described in paragraph (b)(1) of this section or a study described in paragraph (b)(2) of this section.

(1) Information which concerns an incident in which:

(i) The registrant has been informed by municipal, state, or federal public health officials that a pesticide product may not perform as claimed against target animals.

(ii) The possible failures of the pesticide to perform as claimed involved the use against animals which pose a risk to human health.

(iii) The registrant has or could obtain information concerning where the incident occurred, the pesticide or product

involved, and the name of a person to contact regarding the incident.

(2) A study which indicates that the pesticide may not perform in accordance with one or more claims by the registrant regarding uses intended for control of animals that pose a risk to human health, including any of the public health pesticides identified in part 158 of this chapter.

(*c*) Pests that do not pose a risk to human health. Information must be submitted which concerns studies described in paragraph (c)(1)of this section, except as provided in paragraph (c)(2) of this section.

(1) A study concerning the performance of any product used to control pests that do not pose a risk to human health if:

(i) The performance of the pesticide in the study was less than that of the performance standard specified or suggested in the Agency's Pesticide Assessment Guidelines for Product Performance (Subdivision G).

(ii) If no performance standard for control of the pest is specified or suggested in the Pesticide Assessment Guidelines, the performance of the pesticide in the study was less than or equal to that of the untreated control.

(iii) The pesticide label does not warn the user that the pest control failure may occur when the pesticide is used under the conditions in which the failure occurred.

(2) If the failure of performance was due to an inadequate pest population to cause damage when no pesticide treatment is used, inclement weather, or other extenuating circumstances, a summary, including an explanation of why the performance failure occurred, may be submitted instead of the study.

(d) Development of pesticide resistance. Information must be submitted which concerns information described in paragraphs (d)(1) and (d)(2) of this section.

(1) Information concerning substantiation of any incident of a pest having developed resistance to any pesticide (both public health and non-public health) that occurred in actual use if:

(i) The survival of the suspected pesticide-resistant pest was significantly higher than that of a known susceptible pest when both the suspected resistant and susceptible pests were treated with the pesticide under the same conditions.

(ii) Biochemical tests or DNA sequencing indicate that the pest is resistant to the pesticide.

(2) Any suspected incident of a pest having developed resistance to a pesticide in actual use must be submitted if:

(i) The incident occurred in the same or an adjacent state as a substantiated incident.

(ii) Both substantiated and suspected incidents involve the same pest.

§ 159.195 Reporting of other information.

(a) The registrant shall submit to the Administrator information other than that described in §§ 159.165 through 159.188 if the registrant knows, or reasonably should know, that if the information should prove to be correct, EPA might regard the information alone or in conjunction with other information about the pesticide as raising concerns about the continued registration of a product or about the appropriate terms and conditions of registration of a product. Examples of the types of information which must be provided if not already reportable under some other provision of this Part include but are not limited to information showing:

(1) Previously unknown or unexpected bioaccumulation of a pesticide by various life forms.

(2) Greater than anticipated drift of pesticides to non-target areas.

(3) Use of a pesticide may pose any greater risk than previously believed or reported to the Agency.

(4) Use of a pesticide promotes or creates secondary pest infestations.

(5) Any information which might tend to invalidate a study submitted to the Agency to support a pesticide registration.

A registrant is not obligated under this paragraph to provide information to the Administrator if the registrant is aware of facts which establish that otherwise-reportable information is not correct.

(b) The registrant shall submit to the Administrator information other than that described in §§ 159.165 through 159.188 if the registrant has been informed by EPA that such additional information has the potential to raise questions about the continued registration of a product or about the appropriate terms and conditions of registration of a product.

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